FALSE AND MISLEADING ADVERTISING

(DENTIFRICES)

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OF MICHIGAN

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HEARINGS

BEFORE A

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EIGHTY-FIFTH CONGRESS

SECOND SESSION

JULY 17 AND 18, 1958

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FALSE AND MISLEADING ADVERTISING
(Dentifrices)

THURSDAY, JULY 17, 1958

HOUSE OF REPRESENTATIVES,
LEGAL AND MONETARY AFFAIRS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D. C.

The subcommittee met, pursuant to call, at 10:10 a. m., in room 1501, New House Office Building, Hon. John A. Blatnik (chairman of the subcommittee) presiding.

Present: Representatives John A. Blatnik, Porter Hardy, Jr., Martha W. Griffiths, George Meader, William E. Minshall, and Jack Westland.

Also present: Curtis E. Johnson, staff administrator; Jerome S. Plapinger, counsel; and Elizabeth D. Heater, clerk.

Mr. BLATNIK. The Legal and Monetary Affairs Subcommittee of the House Government Operations Committee will please come to order.

Today is our opening day of hearings on certain areas of activities of the Federal Trade Commission. We are in this instance concerned with the regulation of false and misleading advertising—as it occurs in the field of dentifrices.

Last year, almost $25 million was spent to advertise the 12 leading brands of toothpaste. (See appendix, exhibit 7, p. 216). The expenditure of this tremendous sum, in addition to promoting toothpaste sales, could be of great public service if it also encouraged better dental hygiene. However, the leading professional dental association contends that much of the current advertising has had an exactly opposite effect. Thus, it is said that claims for "wonder" ingredients in dentifrices lead the reader or TV viewer to believe that regular brushing of teeth is unnecessary—that protection against decay is assured—if you use the right toothpaste.

These advertising claims are said to be usually persuasive with children, especially when stated by a favorite TV personality.

The companies involved are large and substantial. It is reasonable to expect of them a high degree of public responsibility.

In studying this problem, the subcommittee has been most fortunate. The American Dental Association and some of its most distinguished members have examined dentifrice advertising in the light of the most authoritative scientific information now available.

Our first witness this morning is Dr. Ralph Creig of Cleveland, Ohio, who is a member of the council on legislation of the American Dental Association.

Dr. Creig, we welcome you and your colleagues and associates this morning, and we are looking forward to what we think will be very helpful, certainly very interesting testimony which you men will have to present.

So, Dr. Creig, will you begin with your statement? Would you at the outset make a brief biographical, thumbnail sketch of your professional background and your official capacity?

STATEMENT OF DR. RALPH E. CREIG, CLEVELAND, OHIO, MEMBER, COUNCIL ON LEGISLATION, AMERICAN DENTAL ASSOCIATION

Dr. CREIG. Thank you, Mr. Chairman and members of the subcommittee.

Mr. BLATNIK. Mr. Minshall.

Mr. MINSHALL. I think it is fair to point out that without this fine array of witnesses this committee has had before it from Cleveland, Ohio, this committee would really have no excuse for existence. It just attests to the fact it is the best location in the Nation.

Dr. CREIG. That is very kind. It is nice to be among friends.

Mr. Chairman and members of the subcommittee, I am Dr. Ralph E. Creig of Cleveland, Ohio. I am a member of the American Dental Association's council on legislation.

I am accompanied by Dr. Harry Lyons of Richmond, Va., who is a past president of the American Dental Association and a past president of the Academy of Periodontology. Dr. Lyons is also dean of the School of Dentistry of the Medical College of Virginia and a member of the American Board of Periodontology.

Dr. Sholom Pearlman, assistant secretary of the American Dental Association's council on dental therapeutics.

Dr. Walter C. Hess, assistant dean and professor of biological chemistry at Georgetown University Schools of Medicine and Dentistry.

And Bernard J. Conway, secretary of the association's council on legislation.

Others contributing in the preparation of this testimony are identified in the statement.

The American Dental Association welcomes the interest of the subcommittee in dentifrice advertising. There has been a widespread conviction within the dental profession that many advertising claims for dentifrices are misleading and detrimental to the dental health and general health of the public.

It is prosposed to present our testimony in three parts, beginning with a general discussion and background. This will be followed by detailed consideration of the specific advertisements which were submitted to the association by the subcommittee, and, finally, we will offer some suggestions relating to remedial action which the subcommittee may wish to consider.

Dr. Lyons will present the first part of our testimony.

Mr. BLATNIK. Dr. Lyons, will you proceed?

STATEMENT OF DR. HARRY LYONS, RICHMOND, VA., DEAN, SCHOOL OF DENTISTRY, MEDICAL COLLEGE OF VIRGINIA; PAST PRESIDENT OF THE AMERICAN DENTAL ASSOCIATION; MEMBER, AMERICAN BOARD OF PERIODONTOLOGY

Dr. LYONS. Mr. Chairman and members of the subcommittee, my prepared statement is in several sections, the first of which discusses the role of oral hygiene in general health.

Considerations of dentifrices constitute an important segment of the general subject of oral hygiene. It would, therefore, appear appropriate to define the term "oral hygiene."

Hygiene is the science of health and its preservation. Oral hygiene is the science of health and its preservation with special reference to the mouth and the dental structures. Actually, the health service disciplines concerned with oral hygiene are not as limited as this definition might indicate. The mouth and its contained tissues and organs are integral elements of the body, inseparably related to all the other body tissues and organs through a common circulatory system, the endocrine system, the nervous system, body metabolism, interrelated hazards of infection, toxicities, and malnutrition, and a large number of other factors.

The health service professions are acutely aware that—

(1) Numerous so-called systemic factors influence the health status of the mouth and the dental structures and that

(2) Conversely, the oral and dental diseases have important and adverse influences on the general health and welfare.

Oral hygiene is, therefore, a health science with special reference but not exclusive reference to the mouth and the dental structures. This is a very important consideration which should be a basic factor in the evaluation of dentifrices, their formulas and advertising claims.

One example will illustrate this point dramatically. Persons suffering, unknowingly for the moment, serious blood diseases or endocrine disorders related to pathologic pregnancies and noting the early symptom of swollen and bleeding gums are known to have resorted to the use of dentifrices claiming to cure bleeding gums. This is an example of an unwarranted dentifrice claim related to a symptom common to a large number of diseases, some basically dental and others of systemic scope in causation and effect.

In the preservation of health or the prevention of disease many factors are of established value. One of these many factors is sanitation which may be defined as the establishment of environmental conditions favorable to health. One of these environmental conditions favorable to health is cleanliness.

In the establishment and maintenance of hygienic or sanitary conditions with special reference to cleanliness both the dentist and patient play important roles. The dentist practices what is professionally known as coronal debridement. This is an instrumentation procedure by means of which tartar formations, bacterial plaques, stains and other noxious substances are removed from teeth. The patient contributes to his or her mouth cleanliness chiefly by the skill-

ful and judicious use of a suitable toothbrush, with or without a dentifrice, and to varying lesser degrees by the use of dental floss, irrigation syringes, toothpicks, and mouthwashes.

The establishment and maintenance of oral cleanliness is the sine qua non of continuing mouth health. This is axiomatic and pertains with equal force to caries, which is tooth decay, and the periodontal diseases, among others.

In considerations of oral cleanliness, dentifrices are generally regarded as agents adjunctive and secondary to the use of the toothbrush. They are appreciated professionally as adjunctive cleansing agents because of their abrasive and detergent actions. When properly used with a suitable toothbrush these basic dentifrice actions may assist in the removal of accessible stains, plaques, and other foreign substances. Mild flavoring agents make the use of dentifrices more pleasant and attractive, especially to children. Beyond this, no other merits for dentifrices have been scientifically established. Claims to the contrary, however, have been heaped upon the unsuspecting public for ages dating back to the earliest Chinese, Egyptian, and Greek civilizations.

THERAPEUTIC DENTIFRICES

The word "therapeutic" implies a quality or property of preventing or curing disease, in this case dental decay or other diseases of the oral cavity. The therapeutic claims for these dentifrices, as will be shown, are not adequately substantiated, and the term "therapeutic dentifrice" is therefore a misnomer at this time.

Through the ages, men have searched for a panacea for all their ailments. The dental diseases have not been excepted. It is understandable that men might hope to rub a magic substance on their teeth and gums as a panacea for dental disease and pain. The search for such a magic substance has had the attention of many ethical, humanely dedicated scientists. Others, savoring of the notorious barker, have apparently been motivated by the prospects of acquiring a "fast buck" from the ever-hopeful public.

In the search for so-called therapeutic dentifrices many dentifrice manufacturers have engaged in or supported research programs in their own laboratories and in educational institutions. Some of these have been very valuable; others have been woefully inadequate. The findings of some of these research efforts have, on too many occasions, been distorted or exaggerated in connection with the promotional activities of some dentifrice vendors.

Within our own time, we have witnessed promotions of so-called therapeutic dentifrices on the alleged merits of peptic digestants, antiseptics, sulfated detergents, wetting agents, urea, ammonium compounds, chlorophyllin, antienzymes, and compounds of fluorine. One after another of these dentifrices has been promoted with unsupported advertising claims of great promise. None has survived the test of time and usage.

The public has spent millions of dollars for their purchase. This, however, is the least significant of the several considerations related to the unwarranted claims for alleged "therapeutic" dentifrices. More important are such health factors as a false sense of security about dental caries, periodontal disease, bad breath due to diseases of the nose, sinuses, lungs and the gastrointestinal tract, and serious systemic diseases presenting a variety of oral symptoms.

THE HAZARDS OF MISLEADING DENTIFRICE ADVERTISING

Dentifrice advertising of the past few years is characterized by three general themes which run through the promotional material for virtually all these products. The first of these themes, and the one to which most attention has been devoted, relates to the claim that the use of the product will stop dental decay.

The second major theme relates to the elimination of bad breath.

The third is the promulgation of the idea that adequate oral hygiene may be accomplished by using the dentifrice only once a day.

These themes will be discussed in some detail in a later part of the testimony, but let us examine them briefly here and let us look closely at the harm that results from misinformation on the ramifications of these three important things.

I. DECAY PREVENTION CLAIMS

The dental profession as a whole, and the periodontists as a speciality group within the profession, are devoted to the primary task of saving teeth—of preventing loss of teeth. If the dentist can detect a cavity, a lesion of dental caries, while it is still very small he may place a filling or crown which will no only restore the shape of the tooth but will arrest the progress of the disease.

Moreover, because the adjacent susceptible areas of the tooth are also removed and restored at the same time, the treatment of the lesion in the early stages will prevent recurrence of decay or further spread of decay in that part of the affected tooth.

If the cavity is not detected early and if, as a result of misleading information, the patient believes he does not need early dental treatment, then the cavity will grow, and in as short a time as 3 or 4 months the disease may penetrate to the vital pulp at the heart of the tooth and the pulp will die. In this condition there is often little or no pain or discomfort but two destructive processes continue to operate insidiously against the patient's well-being.

The decay process continues to destroy what is left of the crown of the tooth, and the bacteria which have entered through the cavity and killed the pulp now proceed through the canal within the root of the tooth to attack the underlying tissues deep within the jaw. The infection which follows may be manifested in the form of an abscess, or a more diffuse infection of the bone may ensue. In some cases osteomyelitis may develop. And in some cases the invading bacteria or their toxins may be transported by way of the blood stream to infect or destroy other parts of the body.

All these things may follow because dental caries, among other things, creates portals of entry to our bodies and is therefore a disease having significance in relation to the health and welfare of our entire bodies and not just to the teeth.

Many health problems related to what we know as "focal infection" are, in the above manner, related to tooth decay and may follow the neglect of cavities if the individual is led to believe that he is being protected.

When the dentist can do nothing more, he must extract the tooth. When dental caries has ravaged the entire mouth, all the teeth may have to be removed. This situation is sad enough when it strikes us in our later years, but we have many times witnessed the pitiful

spectacle of young adults and even children who have lost all their teeth through rampant dental caries. There is no recourse for these individuals but to wear artificial dentures for the rest of their lives. The emotional impact of this disaster upon younger people often affects adversely the course of their entire adult existence.

The false promise of immunity from dental decay, which is held out by so many dentifrice advertisers, is surely a contributing factor in encouraging the neglect which leads these innocents into this sorry situation.

During all this time the patient may attribute the accompanying discomfort to other factors, especially if he believes he is safe and secure against dental decay because he is using a toothpaste that is advertised so emphatically as a sure protective agent against the disease.

Dentists more than any individuals would welcome a dentifrice that could prevent or arrest decay when used in the home, but no product available today is capable of satisfying this need.

II. BREATH ODOR CLAIMS

The second point relates to "bad breath" or halitosis, as it is often called. (See appendix exhibit 8, p. 217.) Undoubtedly, much of the odor which emanates from the mouth when we breathe may arise from the decomposition and putrefaction of food residues about the teeth and on the rough surfaces of the tongue. The mouth swarms with bacteria, the descendants of the microbes which began to take up residence there shortly after the infant took its first drink of milk. These bacteria survive on the food particles that cling to the oral surfaces and particularly in the relatively inaccessible places between our teeth. Proper oral hygienic habits, regularly practiced, can remove most of the food residues and the bacteria then have little material from which to produce their offensive end products.

This is one basis for the recommendation, which the American Dental Association endorses, that the teeth should be brushed immediately after eating and not just once a day. If the patient is in good general as well as dental health, bad breath will be controlled adequately by this means alone. A dentifrice may help in this situation by providing assistance to the toothbrush, in the form of a foaming agent and a mild abrasive, but the operation is essentially one of cleansing the oral structures.

The flavoring agents that are a part of almost every dentifrice many encourage the regular use of the brush and, by providing an odor of their own, they may leave an impression of freshness or sweetness of the breath. They may also mask and cover up the residual odor that may persist after the cleansing procedure.

The odor-masking effect of dentifrices, however, can often work to the detriment of the patient's health, because in many, many cases the offensive odor is a warning sign of a situation far more serious than the mere presence of residual food particles in the mouth.

In periodontal disease, or pyorrhea, as it is often called, the inflamed gum tissues and the supporting tissues about the roots of the teeth liberate and exudate and frequently discharge pus continually. These fluids, if they are not already malodorous when they reach the oral cavity, provide a steady source of material for the putrefactive

mouth bacteria to degrade and from which they will produce odoriferous products.

The odor in this case is an important warning that a disease is in progress and requires prompt attention. If the odor is masked by a toothpaste or other means, the unfortunate patient may not seek treatment until the disease is advanced to a state in which the underlying bone has been destroyed, the teeth have become loosened and little if anything can be done to save them. To encourage the use of an odor-masking dentifrice in such cases is to encourage the consumer to delay treatment until it is too late.

Bad breath frequently is a sign of diseases that no amount of toothbrushing can cure. It will not disappear until its causes have been eliminated. If the odor comes from chronically infected sinuses, masking it will only delay much-needed treatment. It may arise from bronchiectasis, a fairly common infectious condition of the lungs, or from certain tumors or other diseases of the lungs—all of which will become worse as long as treatment is delayed by masking the bad-breath symptom with toothpaste.

Many nasal infections cause had breath. Gastrointestinal disorders and other systemic diseases may go undetected and may insidiously establish highly dangerous beachheads while the individual blithely continues to treat the symptoms of the disease by applying a toothpaste which, he has been assured, will eliminate bad breath. The acetone odor of the untreated diabetic is a specific example in point. Certainly this form of assurance, designed to create this false sense of security, misleads the public to the detriment of its health and well-being.

III. CLAIMS FOR THE ADEQUACY OF ONCE-A-DAY BRUSHING

The third point which is of concern to us is of special concern to the periodontal specialist. I have indicated to you that toothbrushing should be performed regularly after meals to remove the food residues which constitute the soil in which oral bacteria thrive and multiply. Food residues also provide a source of mechanical irritation and chemical irritation in addition to providing a pabulum for bacteria. In patients who are susceptible to periodontal disease, the tissues at the edge of the gums at the necks of the teeth become inflamed and we have the condition which is known as gingivitis and is frequently the precursor of further periodontal involvement.

In a clean mouth, and especially after the dentist or the periodontist has removed tartar deposits and corrected other predisposing factors, gingivitis can be prevented by the diligent practice of a good oral hygienic regimen. The dentist instructs his patients carefully in this regard, and important emphasis is placed upon the necessity for regular brushing, preferably after every meal, and in some cases additionally at other times during the day. The brush removes the residues which tend to irritate these sensitive gingival tissues, and some authorities believe also that the massaging action of the toothbrush provides another important effect which promotes the integrity of the gums.

The gum-line areas must be cleansed at frequent intervals and dentists emphasize the importance of maintaining the frequency and regularity of the hygiene schedule. Not only for periodontal pa-

tients but for the public at large, brushing three times a day after meals is recognized as a prime requisite for good oral hygiene.

We are, therefore, deeply disturbed by dentifrice advertising material which encourages the public to disregard measures that we consider to be minimal requirements for oral health, and which recommends instead that the use of a particular toothpaste only once a day provides a good or an even more effective substitute.

Some of this advertising goes so far as to imply that sweets may be eaten with impunity throughout the day, provided only that the toothpaste in question has been used just once in the morning before breakfast.

This vicious suggestion flies in the face of all that has been done by the health professions to educate the public about hygienic and dietary measures for protecting the teeth against the ravages of decay and the periodontal diseases.

There are no shortcuts to dental health at this time, and to mislead the public in this regard is to work deliberately against the public welfare. We are concerned even more deeply with the indication that the use of this kind of detrimental recommendation in advertising already is being extended to the promotion of products which until recently were not promoted in this fashion. Experience with dentifrice advertising of the past leads us to suspect that this line of promotion will soon be adopted by nearly all dentifrice manufacturers.

The unwarranted claims of so-called therapeutic dentifrice vendors provide interesting material for detailed critical evaluation, which we would like to present at this time.

Dr. Pearlman of the American Dental Association's Council on Dental Therapeutics will offer this testimony.

Mr. BLATNIK. Thank you very much, Dr. Lyons.

Dr. Pearlman, will you proceed with your statement?

STATEMENT OF DR. SHOLOM PEARLMAN, ASSISTANT SECRETARY, COUNCIL ON DENTAL THERAPEUTICS, AMERICAN DENTAL ASSOCIATION

Dr. PEARLMAN. Thank you. Mr. Chairman and members of the subcommittee. I shall summarize the material contained in my prepared statement which is designated as part II of the brochure you have, and I ask, Mr. Chairman, that the complete statement be included in the record, along with these supplemental comments which are referred to occasionally in this statement.

Mr. BLATNICK. Without objection, so ordered.

(The prepared statement of Dr. Pearlman follows:)

STATEMENT OF DR. SHOLOM PEARLMAN, ASSISTANT SECRETARY, COUNCIL ON DENTAL THERAPEUTICS, AMERICAN DENTAL ASSOCIATION

PART II. DISCUSSION OF SPECIFIC ADVERTISING CLAIMS

I should like to begin this part of the testimony by presenting a brief summary of the two major dental diseases with which we are mainly concerned: dental caries and periodontal disease.

Dental caries afflicts some 95 percent of the population and is the primary single cause of tooth loss before the age of 35. Out of a hundred years of research on the cause of tooth decay, we have not yet found a complete explanation, but a concept of the disease has emerged with sufficient reproducible corroborative evidence to merit its acceptance as a sound working theory.

THE CAUSES OF TOOTH DECAY

1. The role of bacteria

It is now generally believed that dental cavities form as a result of the operation of several factors. Soon after a tooth erupts through the gums, it becomes covered by a film called the dental plaque. The plaque consists of a feltlike mass of bacteria, food residues, and cellular material which has been shed by the oral soft tissues—all embedded in a filamentous meshwork which adheres firmly to the enamel surface. The plaque is continually changing as bacteria die and are replaced and as parts of it are dislodged by chewing and brushing. It is heaviest in the pits and fissures of the biting surfaces and in the relatively inaccessible places between the teeth, and it is these areas in which cavities most frequently begin to develop. The plaque, then, is a highly active and luxuriant mass of living organisms capable of performing all the chemical reactions that such organisms usually perform. The mouth provides moisture and warmth, and food, vitamins, and all sorts of nutrients to perpetuate the plaque under almost ideal conditions.

2. Sugar and acid formation

Many of the plaque bacteria are of the class of organisms that ferment carbohydrate substances and form acid from them as an end product. The industrial manufacture of lactic acid and other acids depends on exactly the same process, utilizing the chemical factories within the bacteria to ferment sugar and starchy starting materials under controlled conditions. In the dental plaque, as in the test tube and the industrial fermentation vats, sugars such as sucrose and glucose are fermented very rapidly, so that, following a rinse with a 10–percent sugar solution, acid formation may begin to be observed within a minute or 2, and it persists for as long as 30 minutes, depending on individual conditions. Acidity is usually measured in terms of pH units, and, without going into this term in detail, it will suffice for this discussion to remember that the more concentrated the acid, the lower will be the pH value. Water is at pH 7 (neutral); vinegar is at about pH 3.5; and the strong acid in your car battery is at less than pH 1.

The enamel of the tooth is largely mineral, and consists primarily of a form of crystalline calcium phosphate called hydroxyapatite, with lesser amounts of calcium carbonate and other substances. The mineral part of the enamel is bound together in a matrix of organic material, much as the tiles in your bathroom floor are held in a matrix of cement. The hexagons of enamel, however, extend in columns or rods clear through to the underlying dentin of the tooth.

Now, when sugar reaches the plaque, as it does in quantity after a sweet dessert, for example, the bacteria immediately begin to turn it into acid. The pH of the plaque drops from the usual level of about 6.5 or 7 to as low as pH 4 in some people. The acid that is formed attacks the mineral salts of the enamel, and a small quantity is dissolved away. When this process is repeated again and again, a cavity begins to form. Certain protein-destroying bacteria in the plaque may play a contributory role in dissolving the organic cement substance, but, on the basis of overwhelming scientific evidence, acid formation appears to be the primary factor in the decay process.

After the hard and relatively insoluble enamel has been penetrated, the dentin, which is less highly mineralized and is more like ivory or bone, is destroyed rapidly. Eventually, the pulp is reached and the tooth dies.

This, essentially, is the story of how cavities form in our teeth.

THEORIES OF DECAY PREVENTION

1. Reduction of dietary carbohydrate; brushing after meals

It is clear, theoretically, that we should be able to interrupt the decay process in several ways. We can, first, starve the system by restricting our intake of carbohydrates. This treatment has been very successful, and is practiced by many caries-control clinics in this country. When all fermentable sweets are eliminated and the total carbohydrate intake is restricted to about 50 calories per day, dental caries can be arrested. (Starchy foods, like potatoes, rice, or bread, are not so readily converted to acid as are sugars.) This logical and clinically proven procedure is the basis for the time-long dental practice of urging the public to cut down on sweets.

Sugar sources for acid formation may also be removed by prompt brushing of the teeth as soon as possible after eating. Dentistry has long advocated this

hygienic measure, also. As has been pointed out in previous testimony, the brushing is what counts, and the toothpaste or powder is useful only as an aid to the toothbrush in cleansing the oral structures.

2. Removing the acid-forming bacteria

The chain of events might be broken in a second way, by attacking the bacteria in the plaque. Unfortunately, no safe agent is now available that will kill bacteria and sterilize the mouth without damaging the tissues, and such a mechanism has not yet been applied successfully. Some experimental work with penicillin and, more recently, with the antibiotic tyrothricin in a dentifrice may provide promising leads to future success along this line.

It will be well to point out here that, unlike diseases like malaria or influenza or tuberculosis, no single kind of bacteria has been shown to be the direct cause of dental decay. We know that lactobacilli, bacteria of the same family as those which turn milk sour, are found in large numbers in the saliva and plaques of people in whose mouths the decay process is most active. We know, also, that the lactobacilus count goes down when caries activity subsides. But we cannot transmit decay from one person to another by inoculating lactobacilli from one mouth to another. There are far and away more acid-producing streptococci than lactobacilli in the plaque and in saliva, and acid is formed more rapidly by some of these streptococci than by lactobacilli. It may be that, once a cavity begins to form, it provides an ideal nesting place for lactobacilli, and they begin to thrive more abundantly in the mouth when they are sheltered in these cavities and spaces; in that situation, they would undoubtedly contribute to cavity formation by fermenting sugar, along with the other acid-forming bacteria. Nevertheless, because lactobacilli are relatively easy to isolate from saliva and to identify on a bacteriological growth plate, the lactobacillus count has come to be used pretty widely as a convenient and fairly reliable indicator of caries progress. When a caries-active patient is placed on a low-sugar diet, for example, to control the progress of the disease, he is held to that diet until the lactobacillus count reaches a certain low level, and then starches and some sweets are gradually introduced in moderation into his diet.

3. The antienzyme theory

The process of cavity formation is, theoretically, vulnerable at a third point: interference with the enzymes that carry out the chemical reactions by which sugar is converted to acid within the bacterial cells. This has been the objective of the so-called antienzyme dentifrices. More than a dozen enzymes operate in a sort of chain or "bucket brigade" to pass the sugar molecule through a series of well-defined chemical conversions down to lactic and other acids. If this chain is disrupted at any stage, acid production will stop.

Enzymes are large protein molecules, and they can be inactivated in a number of ways. Many foaming agents and synthetic detergents can inactivate enzymes in the test tube, and either stop the fermentation process, or stop a more vital enzymatic process in the cell which may result in the death of the organism. The sulfa drugs appear to act specifically, in a manner which is similar to the latter mechanism. Iodine and other antiseptics and germicides act more generally on a variety of protein enzymes.

4. Neutralization of bacterial acids

There is a fourth possible method of breaking the chain of events that lead to decay: Neutralize the acid before it attacks the enamel. So far, attempts to prevent decay with alkaline or ammonia-liberating dentifrices have not met with great success.

5. Fortifying the decay resistance of the teeth

The fifth and last theoretical approach which we need to discuss before we consider dentifrice claims is the fortification of the tooth substance against the dissolving effects of the acid. The mechanism by which fluoridated water exerts its beneficial effects has not been clearly elucidated, but it appears that decreased enamel solubility may be an important factor. It appears that, if sufficient fluoride is incorporated into the tooth minerals while the teeth are developing, the enamel of those teeth is less soluble and more resistant to acid attack. This may also be the reason for the modest reduction in dental caries that frequently follows the application of sodium fluoride solutions to children's teeth by the dentist. As we shall see, this idea forms the basis for some of the claims that are made for fluoride-containing toothpastes.

This, then, is a capsule summary of what we know of the decay process and some of its vulnerable points.

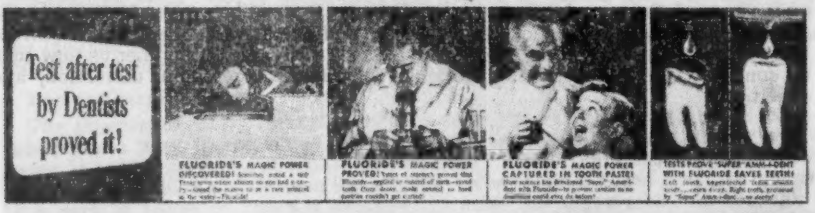
PRACTICAL VERSUS THEORETICAL CONSIDERATIONS

It must be emphasized that rational treatment or prevention of a disease cannot depend on mere theoretical considerations alone. Just as the proof of the pudding is in the eating, the test of a caries-preventing agent is its actual effectiveness in reducing or preventing decay in human beings, not experimentally, but under the conditions in which it will be used by the patient. The council on dental therapeutics, which for nearly 30 years has been evaluating drugs for the dental profession, demands this kind of proof for every item which comes to its attention for consideration. While some dentifrice research may appear to indicate promising lines of progress for the future, it is the council's stated opinion that no dentifrice available today has been demonstrated to be of significant value in preventing oral disease. In most cases where some suggestive evidence has been produced, the council has found that the advertising claims exaggerate, inflate, and otherwise distort the limited scientific findings to the point where the unsophisticated consumer, and even the dentist with his wider knowledge of the subject, is grossly misled and flatly deceived. Let us now turn to some of the more striking examples of this exaggeration, distortion, and deceit.

MAGICAL NEW FLUORIDE TOOTH PASTE

Saves Your Teeth from Decay

BY PREVENTING CAVITIES FROM FORMING!


Test after test by Dentists proved it!
FLUORIDE'S MAGIC POWER DISCOVERED!
FLUORIDE'S MAGIC POWER PROVED!
FLUORIDE'S MAGIC POWER CAPTURED IN TOOTH PASTE!
TESTS PROVE "SUPER" AMM-I-DENT WITH FLUORIDE SAVES TEETH!

FIRST and ONLY Tooth Paste containing All 3 of the best decay-fighters known!

1. FLUORIDE 2. AMMONIATED 3. ANTI-ENZYME 'SLS'

This is the most important dentifrice announcement in years! For it tells how dentists discovered the magic of fluoride...how they *proved* this amazing substance actually *saves teeth from decay!*

Fluoride's remarkable ability to prevent cavities was first noted in a tiny Texas town where there was almost *no tooth decay at all!* Why? Nature had blessed the water supply with fluoride.

A startling reduction in decay was also made when dentists began applying fluoride directly to teeth of children. Now comes the most thrilling news of all!

Today, science has finally discovered how to capture the magic of fluoride in a new tooth paste...so every family, *everywhere*, can save teeth from decay this amazing new way!

Yes! Stores everywhere now have magical new "Super" Amm-i-dent Tooth Paste containing fluoride. It's a "super" tooth paste that offers "super" protection against decay...both for adults and children 6 or over.

America's First Fluoride Tooth Paste!

Brand-new "Super" Amm-i-dent is the *first* fluoride tooth paste available to all America...and is the *only* tooth paste that gives you *all three* of the most effective decay-fighting ingredients known: (1) Fluoride, (2) Ammoniated, (3) Anti-enzyme 'SLS'. All three of these wonderful "decay-fighters" are now contained in this one new "super" tooth paste.

No other tooth paste—no, *not one*—offers you this great *triple protection* against decay. And...while saving your teeth from decay so remarkably, new "Super" Amm-i-dent with fluoride also sweetens your breath and restores the natural beauty and brightness of your teeth.

How "Super" Amm-i-dent with Fluoride Conquers Tooth Decay!

New "Super" Amm-i-dent with fluoride works its magic all day long by *strengthening* permanent teeth—inside and out. It makes tooth enamel so much stronger, more resistant to decay, that cavities couldn't even get started in most cases after once tested!

To give yourself and your family this "super" protection against decay, get new "Super" Amm-i-dent containing magical fluoride. It's the brand new paste...with the grand new taste...in the new red carton! Available now!

"SUPER" AMM-I-DENT with FLUORIDE

DENTIFRICE ADVERTISING

I. Super Amm-i-dent with fluoride

Here is an ad for Super Amm-i-dent with fluoride. It first appeared in the autumn of 1955, when the fluoride toothpaste boom was building toward its peak. Let us pass over, for the moment, the obvious "puffery" of the top slogan in which it is claimed to be a magical toothpaste. I should like you to look at this statement: "Saves your teeth from decay." To me, and to anyone who sees this advertisement, this states with absolute certainty and conviction that I will have no more cavities whatsoever if I use this toothpaste. In the next line it says that it does this remarkable thing "by preventing cavities from forming." I think there can be no doubt that these statements create the impression of an absolute guaranty of 100 percent protection against decay, for everybody.

We had not seen any reports in the scientific literature to support this claim, but it is understandable that, with competition so keen in the toothpaste field, the manufacturer may have released the product and the ad on the basis of unpublished data in his files. When the product first appeared, in July 1955, we wrote to the Block Drug Co. and asked for supporting evidence. In reply, the firm wrote that the active ingredients were: Urea 13 percent; sodium N-lauroyl sarcosinate, 1.7 percent; and sodium fluoride, 0.1 percent. We were told, also, that clinical studies were not yet complete, but that laboratory screening tests had shown, among other things, that the addition of fluoride to the original Amm-i-dent formula did not interfere with the action of the ammonia-liberating compound urea, already present in the dentifrice.

The council had already evaluated the old Amm-i-dent and had classified it in group C which means that the council considered the available evidence to be inconclusive and inadequate to permit a sound scientific evaluation. Now the firm was telling us that the new product, with fluoride, was not any worse than the original.

To this day we have seen not a single report of a clinical study of Super Amm-i-dent with fluoride, either good, bad, or indifferent. As far as we know, the clinical program mentioned in the firm's letter 3 years ago has still not been completed, and we don't know where or how it is being conducted. Yet, in October 1955, this ad proclaimed that "Test after test by dentists proved it." We know of not one single dentist who has even tried to prove that Super Amm-i-dent with fluoride "saves your teeth from decay."

The lesser statements, which appear in small type, make other unsupported claims. We know that water fluoridation will help to prevent decay in the general population and there are years of study and a vast amount of irrefutable evidence, compiled by impartial investigator, which establish its worthwhile effectiveness and its safety. This ad says that the "magic of fluoride" (and there is nothing magic about it), as demonstrated in water fluoridation studies, has now been captured in this toothpaste "so every family, *everywhere*, can save teeth from decay this amazing new way!" No proof has ever been offered for this claim. Fluoridated water, as was pointed out, appears to build decay-resistance into the teeth if it is consumed while the teeth are still forming within the child's jaws. Once they have formed, the resistance-building effect of waterborne fluoride can no longer operate in the same way. And no one yet has shown that by brushing with this dentifrice, containing 0.1 percent sodium fluoride, tooth resistance can be built up and decay can be eliminated. Nevertheless, this ad declares, in the second column, that "New 'Super' Amm-i-dent with fluoride works its magic all day long by strengthening permanent teeth—*inside and out*. It makes tooth enamel so much stronger, more resistant to decay, that cavities couldn't even get started in case after case tested!"

If the facts were available, you would think the manufacturer would hasten to let us know. We have not heard from the firm on these matters since 1955, and we have not been able to find a report of a single one of the cases referred to.

There are many other points that we could discuss before leaving this ad, but I would like to take time only for one, which appears to be a deliberate attempt at deception. Examine the right-hand picture. The caption says "Tests prove 'Super' Amm-i-dent with fluoride saves teeth! Left tooth, unprotected from mouth acids * * * *eaten away.* Right tooth, protected by 'Super' Amm-i-dent * * * *no decay*!"

Most of you may remember seeing a television demonstration of this test. Any high-school chemistry student could spot the fallacy here. In the container above the left tooth there is supposed to be acid. After it drips on the tooth for a time, the crown is dissolved away. This experiment can be demonstrated in the laboratory with ease. It is a simple decalcification process, but is not decay. In the experiment on the right, however, the solution is cloudy because toothpaste has been added to "protect the tooth." Now toothpastes contain abrasives that are either phosphates, carbonates, or other insoluble salts of calcium, magnesium and other elements. All of these salts have one thing in common that is important to this discussion, that is they will neutralize acid. In the right-hand picture, then, we see a drop falling on the tooth. It is extremely unlikely that this drop would contain enough free acid to dissolve a material as soluble as ordinary chalk, let alone dental enamel. With a few calculations and simple chemical dilutions anyone could set up an experiment like this as an amusing trick. In advertising, however, it has little entertainment value.

In the analysis of this advertisement, I have touched only on some of the highlights. I think you may agree that this is a clear example of false, misleading, and deceptive advertising.

Before we go on, I should like you simply to note that this product also contains "antienzyme 'SLS,' " sodium lauroyl sarcosinate. We will hear more about this "antienzyme" factor in a little while.

Now... in its most effective toothpaste form
ONLY BRISK TOOTHPASTE
gives you the same fluoride dentists use
the same
tooth decay fighter
proved for 10 years
in drinking water!
Of the many fluorides, only Brisk's fluoride is so widely used and approved by medical, dental and public health authorities!
All fluorides in toothpaste are not alike
Of the many types of fluoride, Brisk's fluoride has again and again proved itself both safe and effective against tooth decay. It is the fluoride that is most widely used and approved by medical, dental and public health authorities. And only Brisk has it in its most effective toothpaste form.
Brisk makes teeth stronger
Brisk's fluoride has repeatedly proved its amazing ability to strengthen tooth enamel. Concentrates in weak or "soft" spots where decay usually starts. Actually combines with and becomes part of the tooth itself and thus defends against cavities as no other kind of decay-fighter ever could! Daily brushing with Brisk builds stronger, sounder, more decay-free teeth. Keeps breath fresh!
COLGATE BRISK FLUORIDE
WONDERFUL FLAVOR!
No mystic after-taste
Made by COLGATE, world leader in toothpaste

II. Brisk fluoride toothpaste

Here is another sodium fluoride toothpaste, a product of the Colgate-Palmolive Co. In this ad we can see many of the same sort of claims that were in the preceding one. Here we have fluoride " * * * in its most effective form." We get the clear impression that *dentists* use this product in preventing decay because "only Brisk toothpaste gives you the same fluoride dentists use"; and "of the many fluorides, *only* Brisk's fluoride is so widely used and approved by medical, dental, and public-health authorities!" Notice how carefully the ad avoids saying outright that dentists use Brisk toothpaste or that health authorities approve Brisk toothpaste. If these statements were made they would be absolutely false, of course. But it seems that the advertisers have no scruples about making statements that are only deceptive and clearly misleading. How many potential customers do you think will read the "fine print" and will be aware of the subtle distinctions that must be made?

Brisk is claimed to contain "the same tooth decay fighter proved for 10 years in drinking water!" Water fluoridation has been studied for longer than 10 years, but no 10-year study or 5-year study or not even a 1-year study has been reported which might indicate that Brisk toothpaste will prevent decay—at least, we have not been able to find any reports of this nature.

We may note in passing, such claims as "concentrates in weak or 'soft' spots where decay usually starts," and "daily brushing with Brisk builds stronger, sounder, more decay-free teeth." Some extensive comments have been prepared in written form on these and other misconstructions of facts, and we would like to submit them to you for the record where they may be studied at leisure. The important thing is that in this advertisement there is a clear attempt to capitalize on the impressive and sound scientific findings that form the basis of water fluoridation and to deceive and mislead the reader into accepting this toothpaste preparation as a convenient and an even better substitute for that public health measure. We believe that the false sense of security which this kind of advertising engenders constitutes, on the contrary, a significant public health menace.

How a shattering Boorish toothpaste is bringing new hope to every man, woman and child in America

One Billion Unfilled Cavities Must Be Wrong!

CENTERVILLE DENTAL CLINIC

"Look, Mom—no cavities!"

Crest Toothpaste stops soft spots from turning into cavities—means far less decay for grownups and children.

Crest

III. Crest toothpaste with fluoristan

The most broadly advertised fluoride dentifrice is Crest toothpaste with Fluoristan, which is manufactured by the Procter & Gamble Co. This product is promoted extensively in television and radio mediums and in print ads in almost all the important publications on a nationwide basis. This advertisement is one of a series which is currently being used. The pattern in these ads is the same, but the textual material in finer print on the left side changes, as does the artwork.

The theme of these ads is "Look, Mom—no cavities!" This appears in boldface type here, and is also featured with clear emphasis in the television commercials. This ad conveys the message that because this child used Crest his dentist could not find a single new cavity at the examination from which the youngster has just returned. It carries the clear implication that everyone who uses Crest can have the same thing happen to him and that if your dentist has found cavities at your last examination you should use Crest and eliminate the problem completely. "No cavities" means nothing but 100-percent freedom from decay.

If the reader of the ad reads the smaller print below this slogam, he may find that some qualification of the claim is presented toward the end of the section, where it is explained that what goes before "means far less decay for grownups and children." In parts of the fine print on the left side the ad also refers to "*far less new decay.*" Neverless, the strongest impact of this ad is in the slogan "Look, Mom—no cavities!" and this, with the interferences to which it is inseparably bound, constitutes at best both a gross exaggeration and a misleading distortion.

Crest toothpaste is different from other fluoride toothpastes in two important respects. First, the fluoride used in this product, covered by the trademark "Fluoristan," is stannous fluoride, that is, tin fluoride; the others contain sodium fluoride, a different chemical compound. Secondly—and this reflects to the credit of at least one division of the Procter & Gamble Co.—a substantial amount of research has been supported in an effort to develop an effective dentifrice based on stannous fluoride as a caries-preventing ingredient. Out of this research has come the product which is now marketed as Crest.

Representatives of the American Dental Association conferred over a year ago with representatives of the company and with some of the research investigators who have done work in independent universities on some aspects of the development of this toothpaste. We reviewed the chemical and other laboratory studies that first demonstrated the possible usefulness of stannous fluoride as a decay preventive. We reviewed evidence which shows that application of a fresh stannous fluoride solution to the teeth of children by the dentist, under special conditions, apparently results in a lower decay rate on the average. We reviewed laboratory studies which showed that fluoride was taken up by the enamel of teeth, immersed in a slurry of a dentifrice containing stannous fluoride, and that the enamel so treated appeared to acquire some resistence to the action of acids, although the persistence of this effect over a substantial period of time was not demonstrated. We went over the preliminary clinical studies of the use of a stannous fluoride dentifrice in children and young adults over periods of 1 or 2 years, which indicated that some reduction in new cavity formation might be expected from the use of the experimental toothpaste.

At the same time we learned that in almost all of these studies with the early forms of Crest toothpaste, the beneficial effects observed in the first year of use were not nearly so striking the second year. In some cases there appeared to be no significant effect even in the first year. The company realized that stannous fluoride was a very unstable compound when used in a toothpaste, and these failures led them to change the formula from time to time in order to overcome the problem of loss of activity during storage of the product and other equally disturbing changes. The culmination of developments up to the time of that conference was the formulation of the product which was sold at that time as Crest. This Crest toothpaste was not of the same formula as the original Crest, and we do not know whether the product sold today is identical with the one discussed in 1956 or if it has undergone other changes in composition since that time.

The importance of this whole point is that whenever you make the slightest change in the formulation of a product you always have to be sure that that change has not interfered with the activity of the product. In the field of drugs, and in evaluating therapeutic agents, there are many good examples of cases where a desirable therapeutic effect was lost because of a change in the product which might appear to be totally insignificant on a theoretical basis. Even the material from which the container is made may have a destructive effect on the ingredients. With respect to dentifrices, we know that certain abrasives are incompatible with other ingredients and will often inactivate their special effects. This is the sort of problem Procter & Gamble ran into, we were told, in stabilizing the stannous fluoride, and the trademark "Fluoristan" covers not just the tin fluoride but also some of the chemicals with which it is compounded.

When all of this information became known to us, we asked which of the clinical studies sponsored by the company had been done with the toothpaste that was actually being sold to the public. We were told that only in one study was a paste identical with Crest being tested. That study was then still in progress in a Minnesota community. It has now been terminated at the end of 2 years.

The evidence in support of the claims for Crest toothpaste, then, relates to only one completed study. In that study, at the end of the first year the investigators reported that the 248 children who used the Crest formula, containing 0.4 percent stannous fluoride, had about 35 percent less decay on the average than did the 257 children who used a toothpaste which was identical except that it contained 1 percent stannous pyrophosphate instead of stannous fluoride. Fifty-nine percent of the Crest group had no new cavities the first year, which means that 41 percent of them did. In the control group, 44 percent of the children developed no new cavities, without using fluoride toothpaste.

The results of the 2-year examination have not yet been published, but the authors, both dentists, have very kindly permitted us to refer to their data. The results as tabulated show a reduction over the whole 2-year period of less than 16 percent when brushing was unsupervised, and no more than 21 percent when brushing was done in school under some measure of supervision.

The results for the second year alone can only be estimated roughly from these figures, but on the basis of a 35-percent reduction the first year, the figures for 2 years would suggest that there was only at best about 7 percent reduction in the second year alone, and at worst no reduction at all. These figures are, of course, only estimates, but they clearly indicate that the stannous fluoride toothpaste had practically no effect in the second year of its use. We cannot yet tell, from these data, how many children during the second year of the study were able to come home calling, "Look Mom—no cavities!"

This, then, is the background for the current claims for Crest, and for the "Triumph over decay!" theme which announced the premature launching of a distant ancestor of Crest toothpaste on the market a few years ago. We feel that these ads are unquestionably misleading and deceptive. By exaggerating and distorting the modest findings of the scientific investigators these advertisements nullify the very purpose of the investigations. Moreover, they clearly illustrate that the firm has sacrificed scientific integrity for the sake of commercial expediency.

When you can't always brush after meals,
even though it's best – start the day with....
GLEEM GL-70
GLEEM Today as ever ...the toothpaste for
people who can't brush after every meal
JUST ONE BRUSHING destroys
decay-and odor-causing bacteria
PROOF
Only GLEEM has GL-70 to fight decay!
Compton Advertising, Inc.
Gleem—Ad No. 1573
Life—September 9, October 14, 1957
Look—September 17; October 15, 1957
Saturday Evening Post—September 21; October 19, 1957
1 Page, 4 colors

IV. Gleem

Another toothpaste, made by the same firm, is Gleem with GL–70. The advertisements for this product emphasize two main themes: First, that the product is unique in that you only have to brush your teeth once a day if you use Gleem and second, that this is so because just one brushing with Gleem destroys 90 percent of the "decay- and odor-causing bacteria" that live in the mouth. The effect of the advertising is to create the distinct impression that if one uses Gleem first thing in the morning the mouth will be practically free of bacteria all day long and one will therefore be protected securely against decay and mouth odor all day.

The advertisements recognize that it is best to brush after every meal, as indicated in the statement at the top left of this particular ad, but the rest of the ad is carefully calculated to discourage this sensible and often essential oral hygiene practice.

People in this country are not yet used to the idea of carrying a toothbrush with them all day, even though most men carry pocket combs, nail files, and cigarette lighters, and most ladies consider it essential in addition to carry lipsticks, cosmetic cases and other accessories in their handbags. The application of new makeup after a meal is now so routine that no one is offended when a woman goes through a complete makeup routine even in public places. The people who do sensibly use a toothbrush after eating usually do so in the relative privacy of the washroom.

The point is that food residues should be removed from the teeth as quickly as possible after eating. This procedure removes much of the substrate material from which bacteria may otherwise produce acids and enhance the decay process, and from which other bacteria may produce foul-smelling decomposition products and even some irritating substances that may contribute to the development of gingivitis and periodontal disease.

We have clinical evidence to show that decay can be reduced more effectively by brushing after every meal than by brushing only once or twice a day. Moreover—and here the American Academy of Periodontology is very deeply concerned—the accumulations of food at the necks of the teeth along the margins of the gums must be removed as quickly as possible in order to maintain conditions that are best for preventing gum disease and its often disastrous sequellae.

The development of periodontal disease, or pyorrhea as it is still called by many people, can be illustrated very briefly.

The gingivae are the normally pink and firm tissues that cover the submerged portion of the tooth and its bony understructure; the whole structure covered by the gingivae is generally called the gums. For reasons that are still not clear, a number of exciting factors may cause inflammation of this tissue, chiefly at the gingival margin next to the exposed part of the tooth. The inflammation is usually noticed in the form of color change from pink to red, as a result of engorgement of the tissue with blood. The name given to this condition is gingivitis. The inflammed gingival tissue bleeds easily and a common indication of the presence of the disease is "pink tooth brush"—a sign that appears even in the early stages.

Gingevitis can occur as a result of poor oral hygiene, accumulation of food deposits at the necks of the teeth, "traumatogenic occlusion" (when certain teeth receive more than their share of stress and shock during the biting and chewing movements), or spontaneously during pregnancy, or for no apparent reason. Bacteria unquestionably are present in the furrow between the tooth and the encircling gingival cuff, and their destruction by means of chemicals or drugs sometimes afford temporary relief. But in the normal course of events, calculus (tartar) is formed in the gingival crevice (perhaps through the indirect activity of some bacteria). These deposits cause the gingivae to recede rootward in a sort of "foreign body reaction", which is usually accomplished by further inflammatory changes (see Figs. 1 and 2). This is the beginning of serious periodontal disease. As the disease proceeds, secondary infection and exudation of pus ensues. The supporting jawbone is progressively reduced in size until eventually the tooth loses its bony support and is either exfoliated or is ex-

tracted when the condition becomes hopeless (see figs. 3 and 4). The bone and the overlying tissues may then regenerate to some extent, but seldom is the alveolar ridge restored to its original height and condition. This makes the retention of artificial dentures a difficult and sometime impossible task.

The dentist and the periodontal specialist can arrest the progress of gingivitis and periodontitis by removing some of the causative factors, that is, by eliminating traumatogenic high spots on the teeth, correcting the patient's bite, carefully removing calculus deposits from above and below the gumline, or by surgical elimination of the periodontal pockets. But to maintain a clean and hygienic state of gingival health and to prevent recurrence of the disease, the patient must follow a rigid and regular regimen of toothbrushing and mouth care. The food debris must not be allowed to accumulate in the critical areas, and the dentist usually instructs the patient to clean his teeth at least three times a day after meals and sometimes even more often.

Periodontists for years have devoted a great deal of time and patient instructional efforts toward educating patients in the proper use of the toothbrush and in the necessity of brushing the teeth at least after each meal. All this educational work is being broken down by those toothpaste ads which say, in effect, "Never mind what your dentist says is best for you. With our toothpaste you only need to brush your teeth once a day." This kind of advertising is not only misleading and deceptive, but it is harmful to the public because it encourages inadequate health habits and discourages adherence to sound professional advice. If this trend in advertising is followed by other dentifrice manufacturers, as has so often been the case with other sales themes in the past, the situation will become one of even more serious concern. Some of the recent ads for Colgate dental cream indicate that this manufacturer already has fallen into line. We have seen television commercials which include a statement to the effect that just one brushing with Colgate's provides protection. The dental profession already is hard put to cope with these problems by educational means, and it will be virtually impossible to counteract the effects of more extensive propagation of such detrimental advertising with the limited means available to the profession.

If this point requires further elaboration, we have a recent example of its importance. Here is a recently published copy of one of a series of posters that are being developed by the Bureau of Dental Health Education of the American Dental Association. These posters are intended to provide pictorial ideas without words, for use in kindergarten classes and the lower grades as a basis for discussion at the elementary level. The children are asked to say what story the poster tells. To get an idea of how they will be received by teachers and by the children, a set of the posters was distributed to several teachers in the Chicago area for trial. This one shows a child washing his hands before his meal and brushing his teeth afterwards.

When this poster was presented for discussion, the children quickly understood and agreed that it is a good health practice to wash hands before you eat. But when they considered the last picture there was a great argument about the need for brushing the teeth after eating. They said that certain television characters, in whom they evidently placed a great deal of confidence, always said that you only have to brush once in the morning because the toothpaste had something in it that would protect your teeth all day.

These are the ideas implanted by this kind of advertising in the minds of little children, who are least able to evaluate the statements, and who are at the age when the groundwork is being laid for the formation of lifelong habits.

The claims for Gleem in the area of tooth decay also are misleading and deceptive. The ingredients of GL–70 have not been disclosed, but information received in 1953 indicates that at that time GL–70 was a mixture of sodium monglyceride sulfonate and sodium alkyl sulfate, two kinds of "synthetic detergents." The toothpaste was stated to contain 1 percent of this mixture. We have no information on the present product, and in view of the history of other dentifrices some changes in composition probably have been made over the past 5 years. The data offered in support of the decay claims, however, were based at least in part on tests performed during or prior to 1953.

The claims in this fairly recent advertisement, which are repeated with slight variations in television commercials and elsewhere, indicated that one brushing with Gleem destroys 90 percent of the oral bacteria. The statement carefully states "* * * up to 90 percent" but it will be seen that the figure "90 percent" is in type about twice as large as that used for the words "up to,"

and the inference will be quite clear to all but the meticulous reader. The pictures representing the bacterial count leave no doubt about what idea the ad hopes to convey: one brushing with Gleem kills almost 100 percent of decay- and odor-causing bacteria. The reader is freely invited to take the bait and draw the obvious inference: that one daily brushing with Gleem stops nearly 100 percent of tooth decay and mouth odor. This suggestion is reinforced in several places through the ad by such phrases as "completely destroys most bacteria," "strikes right at the very cause of decay and mouth odor," "Mouth odor stopped all day" and so forth. The message is unmistakable.

The bacterial tests behind the decay-prevention claims are reported to have been performed in the following way. Before breakfast, subjects brushed their teeth for 1 minute with salt water, all the fluid was collected, and bacterial counting plates were made from a measured part of it. Ten minutes later they brushed with about a half inch of Gleem toothpaste, and the mouth contents were discarded. After another 10 minutes they brushed again with the saline solution and the mouth contents were collected for bacteriological plating. The "before" and "after" plate counts were compared and the difference in count was expressed as "percent reduction." The tests were repeated on successive days so that averages for each subject could be calculated.

Now I am sure you will recognize several fallacies in this procedure. In the first place the test may give an estimate of the numbers of bacteria that were removed in brushing, but it does not tell how many bacteria were destroyed in the dental plaque on the susceptible surfaces of the teeth where the decay process goes on. The fluid that was tested represents only a part of the millions of bacteria in the mouth, and includes those that were dislodged from the tongue, cheeks, and soft tissues as well.

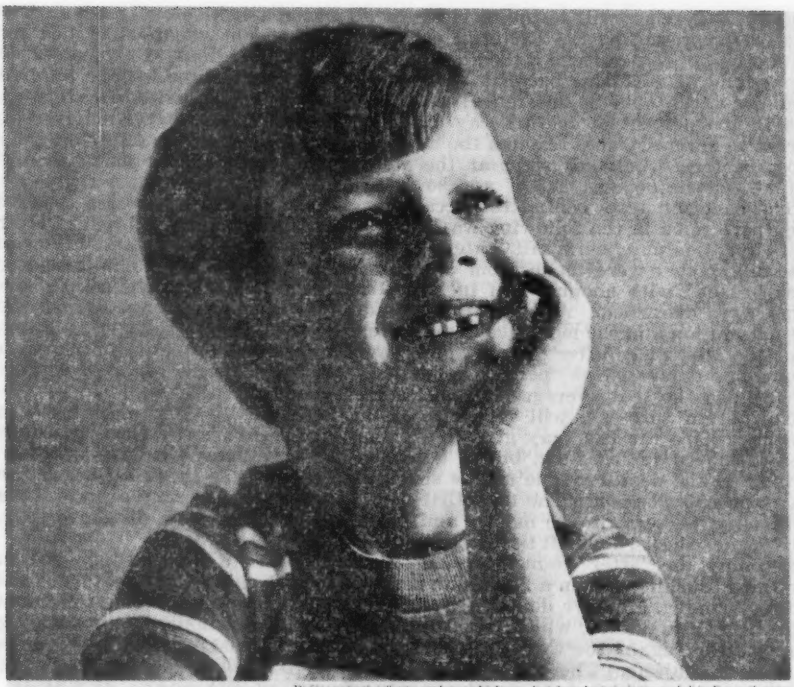
Secondly, the "after" count represents the bacteria that could be dislodged on the third brushing within a 20-minute period, of which the second treatment was with a foaming, abrasive dentifrice. The tests did not employ even a minimum control for comparison, which might have been arranged simply by substituting salt solution again for the toothpaste during the second brushing step, in a number of subjects. There is no adequate answer to the obvious question: What reductions in bacterial count would you get without the toothpaste?

A third fallacy involves the antibacterial or germicidal attributes of the toothpaste. It is well-known that in testing the effects of germicides care must be taken to avoid carrying small amounts of the chemical over into the bacteriological culture tubes or plates. We have examined a statement in which it is claimed that GL–70 "has definite anti-bacterial properties" even when diluted to less than 1 part in 1,000,000 (10 percent $\times$ 1 percent $\times$ 1 : 10,000). It follows that in the fluid from the "after" brushing, which was collected 10 minutes after the use of Gleem, the presence of as little as 1 part of GL–70 per million parts of fluid might affect the growth of the bacteria in the salt water and saliva mixture. The bacterial counts should then certainly be low, since the bacteria in the culture medium would be constantly exposed to a germicidal agent. Evidently no effort was made in these tests to neutralize any residual activity from the GL–70, or even to determine whether there was any appreciable carryover, This is not the sound scientific approach one would expect to be followed in an objective investigation.

From the reports we have reviewed we would not agree that it has been proved that one brushing with Gleem with GL–70 really destroys 90 percent of the bacteria that reside in the mouth. Moreover, it is evident from the bacteriological data, taking into account the inadequacies just reviewed, that in many subjects the apparent reduction of bacterial count often was less than 10 percent, and that only 3.5 percent of the subjects showed an average reduction of 90 percent. The most important criticism, however, is that the method of testing was so unreliable as to make the results almost meaningless.

Even if the advertisements are interpreted literally, on the basis of the actual, carefully chosen words, the statements are not well-supported by scientific facts and are therefore misleading. If the advertising claims are interpreted more broadly to mean that Gleem in some special fashion reduces or prevents decay, or "fights decay" as the ads often say, then the effects are completely misleading because there is apparently no evidence whatsoever that a single clinical trial of this toothpaste was conducted to determine whether its use will afford any unusual degree of protection against the disease.

In summary, then, the advertising for Gleem toothpaste with GL–70 is not only misleading and deceptive, but it is extremely undesirable because it promotes the breakdown of important oral health habits and practices.



Dick's new tooth will get a good start with Ipana . . . best decay-bacteria destroyer of all leading tooth pastes

THIS SPACE RESERVED

for a tooth that must last for 63 years

you: I always make very sure my boy brushes his teeth.

us: That's good. It's even *better* if he uses Ipana with WD-9!

you: What's so wonderful about WD-9?

us: WD-9 is a powerful decay fighter. Ipana with WD-9 destroys decay bacteria *best of all leading brands*, including fluoride tooth pastes.

you: That's fine . . . but if my boy doesn't like the *taste* of a tooth paste, he simply won't use it.

us: Ipana's new minty flavor is a hit with just about everybody! And Ipana does as good a job on your teeth as on children's. Try a tube soon?

• Non-kling cap on tube, hard to lose.
• Tube can stand upright.

New-formula Ipana' with WD-9 destroys decay bacteria best of all leading brands

V. Ipana with WD–9

The antibacterial effects of some of the foaming agents used in dentifrices have been exaggerated in advertising for a great many products. Ipana toothpaste for some years has been promoted on the basis of the alleged caries-preventive properties of its particular foaming agent, WD–9.

In this ad we see a child who has recently lost his first upper incisor tooth. The main caption indicates that the new permanent tooth that will fill the space must last for 63 years, suggesting that special care must be taken to see that the permanent teeth will last a whole lifetime. The inference, of course, is that regular use of Ipana will give the teeth the protection they need to survive that long, and the text material goes on to tell why.

The discussion says that while brushing the teeth is a good practice, "It's even better if he uses Ipana with WD–9," because "WD–9 is a powerful decay fighter."

"WD–9" is the firm's name for sodium lauryl sulfate, a type of synthetic detergent that is employed in several toothpastes as a foaming agent. It has some antibacterial activity, and there is evidence that that activity is not lost when the material is mixed with the other ingredients of the toothpaste. But, as far as we have been able to determine, there has never been a clinical trial of Ipana with WD–9 to show what effect, if any, the use of this product may have on decay in human subjects. We know of no evidence to support the claim that "WD–9 is a powerful decay fighter."

The ad also says that "Ipana with WD–9 destroys decay bacteria best of all leading brands * * *." In more recent ads, and especially in television commercials, it is claimed that Ipana has twice the decay-germ killing power of any other toothpaste. We have already pointed out that terms like "decay bacteria" are misleading because they imply that killing certain bacteria will stop decay. If Ipana is claimed to have twice the decay-germ killing power, then the advertisements may be considered to be just twice as misleading. If one brushing with Gleem destroys 90 percent of the so-called decay bacteria, does Ipana destroy 180 percent. Obviously this sort of advertising is confusing and because it is confusing it will be misleading to many readers.

The bacteriological basis for the Ipana claims are discussed in supplementary material that we would like to place in the record. The reported activity of Ipana was as much as four times greater in some tests than it was in others. With a test so unreliably standardized that a fourfold variation can occur from one day to another, the acceptability of claims for superiority over other brands must certainly be questioned.

The printed ads for Ipana are modest in comparison to some of the television commercials. The visual emphasis and the vocal presentation exaggerate the claims even further. The Bucky Beaver series and other material which is directed to very young children are especially blatant in their exaggeration of the claims. The finality with which Ipana routs the character called Decay Germ and foils his plans to "blast holes in your teeth" is a gross distortion of the properties of the toothpaste. It implies that Ipana has a magic property which gives complete protection against decay. No such property has been demonstrated. The dramatic impact of these commercials on the children establishes false beliefs that for a long time will interfere with the teaching of sound dental health concepts.

No Other Leading Toothpaste

CLEANS
CLEANS
CLEANS

YOUR BREATH *while it*

GUARDS
GUARDS
GUARDS

YOUR TEETH

Like Colgate Dental Cream!

Because No Other Leading Toothpaste Contains GARDOL TO GIVE YOU LONG-LASTING PROTECTION AGAINST BOTH BAD BREATH AND TOOTH DECAY ... With Just One Brushing!

Unlike other leading toothpastes, Colgate's forms an invisible, protective shield around your teeth that fights decay all day . . . with just one brushing! Gives you a cleaner, fresher breath all day, too! Ask your dentist how often to brush your teeth. But remember! No other leading toothpaste* cleans your breath while it guards your teeth like Colgate Dental Cream with Gardol!

SAFE for Children of All Ages! to Use in All Water Areas! Makes teeth whiter—cannot stain or discolor!

Guaranteed by Good Housekeeping

Even When I'm Right— I'm Wrong!

I DON'T KNOW HOW YOU COULD BE SO STUPID, TOMMY! CAN'T A PERSON SAY ANYTHING IN THIS HOUSE THAT YOU DON'T GO AND TATTLE?
BUT, SIS! YOU SAID YOU WISHED SOMEONE WOULD TELL EDDIE!
ANYWAY, I JUST TOLD HIM YOU LIKED HIM, FINE—ONLY FOR HIS BREATH! AND EDDIE THANKED ME! HONEST! HE DID!
WELL, MAYBE IT'S ALL RIGHT, TOMMY! GOODNESS KNOWS, EDDIE'S OLD ENOUGH TO LEARN THE FACTS ABOUT BAD BREATH!

EDDIE LEARNS HOW TO STOP BAD BREATH!
COLGATE DENTAL CREAM WITH GARDOL STOPS MOUTH ODOR ALL DAY FOR MOST PEOPLE—WITH JUST ONE BRUSHING. BECAUSE COLGATE'S WITH GARDOL CLEANS YOUR BREATH WHILE IT CLEANS YOUR TEETH!
LATER—THANKS TO COLGATE DENTAL CREAM
COLGATES AND ME DID RIGHT BY EDDIE SO D-O-G-S AND SIS ARE GOOD BREATH!

Brush Your Teeth with COLGATE DENTAL CREAM... Brush Bad Breath Away!

And Colgate's with GARDOL Fights Decay All Day, Too!

Gardol's invisible shield fights tooth decay all day ...with just one brushing

Colgate's with Gardol stops mouth odor all day for most people . . . with just one brushing! And of all leading toothpastes,* only Colgate's contains Gardol to form an invisible protective shield around your teeth that fights tooth decay all day . . . with just one brushing!

So to fight both bad breath and tooth decay all day, use Colgate Dental Cream with Gardol!

WORLD'S LARGEST SELLING TOOTHPASTE

CLEANS YOUR BREATH WHILE IT **CLEANS YOUR TEETH**

VI. Colgate dental cream with Gardol

According to information obtained periodically from market surveys, the toothpaste that leads the field year after year from the standpoint of sales is Colgate dental cream. This product contains an ingredient called Gardol which is the fanciful name for sodium N-lauroyl sarcosinate. Gardol suggests that the material is there to guard all your teeth.

A discussion of the laboratory tests with this material and the clinical studies that form the basis of the extravagant claims for Gardol in protecting the teeth against decay will be presented in separate testimony. I should like to point out that the Council on Dental Therapeutics has evaluated all of the published evidence and considers it inadequate to support the claims.

These two ads are typical of the promotional material that has been employed for Colgate dental cream over the past few years. Under the picture of the "invisible shield" is the statement that "Gardol's invisible shield fights tooth decay all day * * * with just one brushing." This theme is fortified in several places elsewhere in the ad.

In the major report of the 2-year study which is the strongest basis for the claims, there is no mention of the effectiveness of the product after only one brushing a day. The test groups brushed either twice a day or three times a day with the Gardol toothpaste. The results of these tests, as I have just indicated, were not considered to be conclusive. To the best of our knowledge there has not been a study of the effects on tooth decay of once-a-day brushing with this product; if its use twice or three times a day produced no conclusive results, it is hardly likely that one daily brushing would be any more beneficial.

The invisible shield pictured here is a small replica of the giant invisible barrier that is shown in the television commercials. In the absence of direct evidence it would appear that the shield concept may stem from laboratory tests which, perhaps, show that small amounts of Gardol can be detected on the teeth several hours after a brushing with the toothpaste. Sodium N-lauroyl sacosinate does have antibacterial activity but, as has been pointed out in the case of other foaming agents, the mere ability to inhibit bacterial growth is not the same thing as the ability to prevent cavities from forming. And even if traces of Gardol are found on the teeth some time after the toothpaste is used, it is certain that the original film of the material has been abraded and scraped by the foods we eat so that it is no longer intact. In effect, then, while the Gardol could perhaps be detected on parts of the tooth, the so-called shield might at the same time be shot full of holes.

The impression that this advertising strives to create is that one brushing with Colgate dental cream produces absolutely invulnerable protection all day, and assures 100 percent immunity against tooth decay. The ads we have reproduced here do not convey the full message. One has only to watch one of the television films to get the total impact.

The films explain how Gardol works. In some of them, for example, a baseball is shown being thrown toward the camera; at a critical moment an "invisible shield" stops the ball, with appropriate sound effects, and deflects it harmlessly out of the way. The announcer explains that "just as this invisible shield helped protect us (from the flying object)" Gardol forms "an invisible protective shield around your teeth." in other films the flying object may be a driven golf ball, or a shovelful of dirt, or a tennis ball, and so on. In a current film, after the "invisible shield" has stopped the flying missile from striking a woman and child, the woman raps her knuckles against it to illustrate to the child that the miracle shield is still there. The announcer keeps up his hard-driving message to reinforce the ideas further.

There can be no doubt in anyone's mind that these commercials are trying to tell the world that one brushing with Gardol stops decay cold. No one can miss the finality of that message. And how many can judge whether it is true or not? This line of advertising is nothing but outright deception. The Mighty Mouse series of television commercials, beamed at children several times

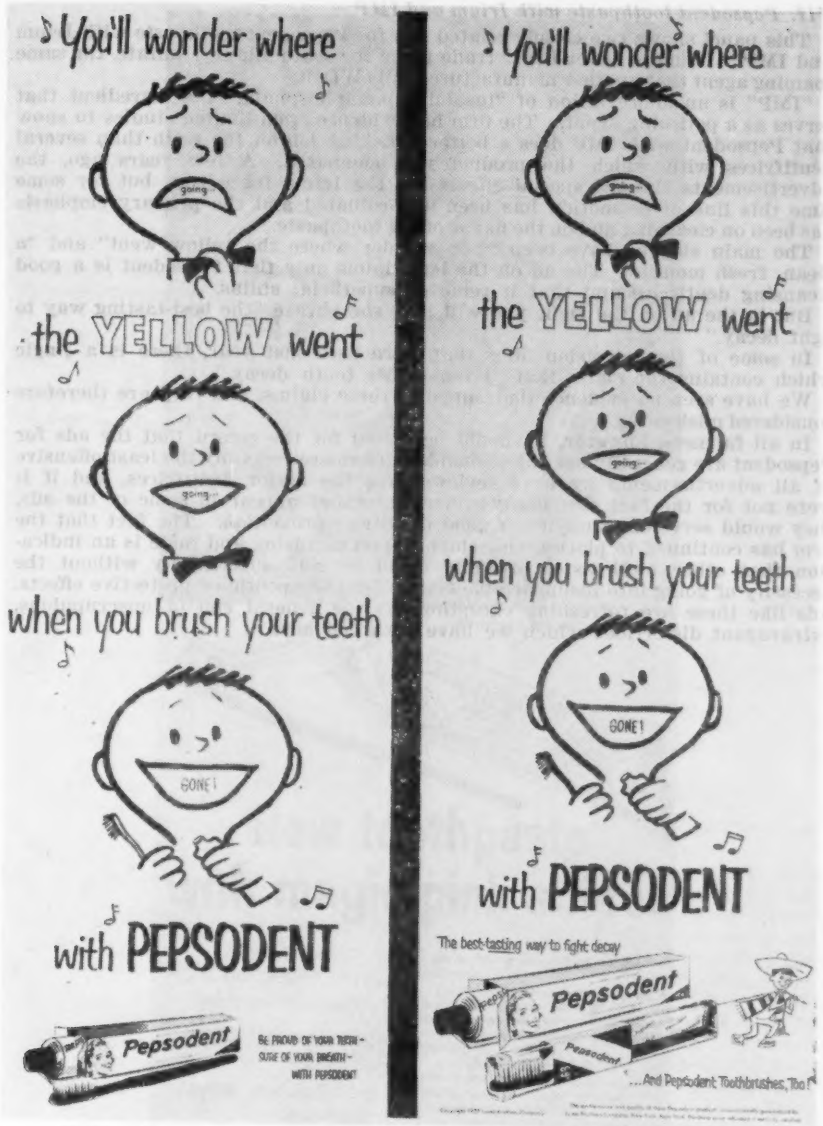
a week, is even worse from the standpoint of ability to confuse, mislead, and establish bad dental health concepts.

Of course, the advertisements make token gestures in the interest of staying within the technical limits. For example, they say "Colgate's with Gardol stops mouth odor all day *for most people*" [emphasis not in original]. The words "for most people" are under-emphasized, though they are of critical importance. Then the ad says "And of all leading toothpastes,* only Colgate's contains Gardol * * *" The asterisk refers to this microscopic print in the lower left of the ad which says "*Top three brands after Colgate's." This, of course, excludes brands like Super Amm-i-dent with Fluoride, which contains sodium N-lauroyl sarcosinate as 1 of 3 wonder ingredients, Sears, Roebuck's toothpaste, Walgreen's and several other less popular brands which contain the same chemical.

In the television films, these and similar qualifying statements are thrown in so inconspicuously that they are sure to be missed unless one is carefully watching for them. This audiovisual sleight of hand is a clear indication of deceptive intent, and the overall effect is definitely misleading.

I might also mention, in passing, the use of the white-coated figure—a woman, in this case—holding a dentist's mirror and talking authoritatively to the patient. This clearly aims at giving the impression that dentists or dental hygenists recommend Colgate's toothpaste and that professional people as a whole support the claims. Nothing could be further from the truth.

It is somewhat shocking to realize that a firm like Colgate-Palmolive, which surely must be aware of the shortcomings of the scientific background for its products, apparently has authorized its advertising department to make deliberate efforts to conceal the facts from the consumer, in the interest of successful sales competition. This is the same firm that has set up and is supporting a division of dental medicine on the campus of Rutgers University, where some excellent research in basic dental science is going on, apparently not related to toothpaste development. This is the firm that for the past few years has donated about $15,000 annually so that senior dental students across the country may receive complimentary copies of the Journal of Dental Research. One may wonder how, in all good conscience, the management can support pure science and philanthropy with one hand, and accept the fruits of public exploitation with the other.


You'll wonder where
going
the YELLOW went
going...
when you brush your teeth
GONE!
with PEPSODENT
Pepsodent
BE PROUD OF YOUR TEETH - SURE OF YOUR BREATH - WITH PEPSODENT
You'll wonder where
going
the YELLOW went
going...
when you brush your teeth
GONE!
with PEPSODENT
The best-tasting way to fight decay
Pepsodent
...And Pepsodent Toothbrushes, Too!

VII. Pepsodent toothpaste with Irium and IMP

This panel shows two closely related ads for Pepsodent toothpaste with Irium and IMP. Irium is Lever Bros.' trade name for sodium lauryl sulfate, the same foaming agent that another manufacturer calls WD–9.

"IMP" is an abbreviation of "insoluble metaphosphate," the ingredient that serves as a polishing agent. The firm has evidence from limited studies to show that Pepsodent with IMP does a better polishing job on the teeth than several dentifrices with which the product was compared. A few years ago, the advertisements claimed special effects for the Irium ingredient, but for some time this line of promotion has been subordinated and the primary emphasis has been on cleansing and on the flavor of the toothpaste.

The main slogans have been "You wonder where the yellow went" and "a clean, fresh mouth." The ad on the left claims only that Pepsodent is a good cleansing dentifrice and that it removes superficial stains.

But in the ad on the right you will note the phrase "the best-tasting way to fight decay."

In some of the television films that were used last year, there is a jingle which contains the claim that "Irium fights tooth decay."

We have seen no evidence that supports these claims, and they are therefore considered misleading.

In all fairness, however, it should be stated for the record that the ads for Pepsodent are generally not objectionable. They are certainly the least offensive of all advertisements we have reviewed for the major dentifrices, and if it were not for the fact that decay-protection claims appear in some of the ads, they would serve as examples of good dentifrice promotion. The fact that the firm has continued to place major emphasis on cleansing and taste is an indication that other toothpastes probably could be sold successfully without the necessity of going into insupportable claims for therapeutic or protective effects. Ads like these are refreshing exceptions to the general run of unscrupulous, extravagant distortions which we have reviewed here.

It keeps your
breath close-up
clean
Comes out striped
Stripe
New toothpaste
with magic pink stripes
STRIPE with
HEXACHLOROPHENE kills bad
breath and decay germs...
better than any leading
toothpaste...
better than any leading
mouthwash...
even better than using both!
Yes, new STRIPE* actually comes out
in pink and white stripes! Those stripes
tell you STRIPE is double magic!
1st, it's the only toothpaste to bring
you Hexachlorophene, the famous germ-
killer so widely accepted by the medical
profession.
2nd, it has the finest cleanser known to
dental science. Tests prove STRIPE de-
stroys millions more bad breath and decay
germs than any leading toothpaste plus a
mouthwash!
A single brushing with STRIPE will
protect you against the cause of decay and
mouth odor hours longer than any other
toothpaste you can buy.
STRIPE's Hexachlorophene seeks out
and destroys germs even in the tiny
crevices where no toothbrush can reach.
STRIPE is safe for everyone, even chil-
dren under six. 100% sugar-free. Tastes
wonderful! Get STRIPE soon.
Guarantee: The performance and quality of STRIPE
Toothpaste is unconditionally guaranteed by Lever
Brothers Co. Purchase price refunded if not satisfied.
Stripe with HEXACHLOROPHENE

VIII. Stripe toothpaste with hexachlorophene

Up to now, Lever Bros. has had only one major toothpaste in the national market—Pepsodent. Early this year we began to see ads for this one—Stripe with Hexachlorophene. Hexachlorophene is a phenolic germicide that is employed widely in germicidal soaps, like Dial soap which contains 2 percent of the compound, and in some baby lotions.

The tube for Stripe toothpaste is cleverly designed so that the paste comes out white with red stripes, resembling a candy cane. One would think that this "gimmick" alone could be relied upon to sell the toothpaste as a more attractive cleansing dentifrice. Evidently the firm did not think so. Hexachlorophene provides the basis for a whole series of antibacterial claims, which in some respects go beyond those we have already reviewed.

Stripe is claimed to kill "bad breath and decay germs—better than any leading toothpaste, better than any leading mouthwash, even better than using both."

The once-a-day brushing theme is employed in even more offensive terms than with other products: "A single brushing with Stripe will protect you against the cause of decay and mouth odors hours longer than any other toothpaste you can buy."

And the claim for specific, penetrating action is expressed emphatically: "Stripe's hexachlorophene seeks out and destroys germs even in the tiny crevices where no toothbrush can reach."

No mention is made of a single clinical test that might show that Stripe actually prevents dental decay in ordinary home use or even under supervised conditions. If such tests have been made, they certainly have never been reported in the scientific literature. We know of no evidence whatsoever which demonstrates that Stripe toothpaste is a decay-preventive agent.

As for the antibacterial claims, hexachlorophene is a very effective germicide, and in the test tube it may be expected that it will destroy bacteria effectively. We do not yet know what laboratory tests were performed by the company to establish a basis for these statements of comparative efficacy. It may be that the well-known facts about the action of hexachlorophene in soap have simply been lifted and transferred to Stripe toothpaste without direct study. Nothing in the literature would lead us to a more generous conclusion.

The effects of this ad are to claim that Stripe is a better decay preventive than any other toothpaste, and to encourage the inadequate practice of brushing the teeth only once a day. The ad is therefore grossly misleading and inherently harmful.

IX. Co-op toothpaste

The last product I will bring to your attention is Co-op toothpaste. Probably you have never heard of it; it is not advertised. This toothpaste is a conventional cleansing dentifrice sold by National Cooperatives, Inc., through co-op stores in different parts of the country.

There are no ads for this toothpaste but I should like to submit for the record a copy of the labeling on the box. I should like to read for you the message that occupies one side panel and is the only printed material on the carton besides the name:

"The best insurance for sound teeth is: (1) Proper diet with plenty of milk, fresh fruits, and vegetables; (2) regular visits to your dentist; (3) thorough brushing after every meal * * *."

This is sound health advice, which is in agreement with the advice of the best professional authorities in the country.

"* * * Thorough brushing cleans the teeth—often no dentifrice at all is required * * *"

This statement is on the carton of a dentifrice package.

"* * * Or an effective and inexpensive dentifrice such as precipitated chalk or a mixture of table salt and baking soda can be used * * *"

These simple and economical dentifrice preparations have been suggested by organized dentistry for years, and they are effective aids to the toothbrush when a mild polishing agent is desired.

"* * * Many users prefer a pleasant-tasting dentifrice, such as Co-op toothpaste, which encourages regular brushing by both children and adults."

There you have an honest appraisal, a clear enunciation of the only things a toothpaste should be expected to do, a sound set of dental health rules for everyone to follow, and a straightforward suggestion for those who may have to operate on a tight family budget.

The cost of a tube of Co-op tooth paste in Chicago was 29 cents when this package was obtained. At the same time, the same size tube of the high-powered "hard sell" toothpastes was offered for 59 cents or more. The material I have presented to you at this hearing is intended to show that, as far as we are aware, there is no conclusive proof that any of the nationally advertised toothpastes will do anything more for the consumer than an ordinary dentifrice like Co-op toothpaste. This rare example of forthright honesty and sincere concern for the welfare of the consumer makes very plain the essential issues in the whole matter.

X. Summary

In conclusion, I should like to summarize these issues.

1. The primary purpose of a dentifrice is to assist the toothbrush in cleaning the teeth. The cleansing process of brushing, with or without a dentifrice, removes potentially harmful food residues, and reduces the opportunity for acid formation which is an important factor in causing tooth decay. Regular brushing also is advocated for the prevention of gingivitis and periodontal disease, and for the maintenance of hygienic conditions in the mouth.

2. Adequate scientific evidence has not yet been produced in support of the special decay-preventive claims that are made for national advertised dentifrices. The presence of various additives in these products has not been demonstrated to produce the effects ascribed to them in the promotional material.

3. The advertisements for most of the major dentifrices are grossly deceptive and misleading. Through the use of half-truths, pseudoscientific statements, and distorted implications they tend to create a false sense of security about dental health. This is harmful because it leads people to neglect sound health habits. In some cases, the advertisements openly advocate disregard for the frequently essential practice of brushing the teeth after each meal.

4. It is obvious that the laws and regulations now in effect are not adequate to control the existing situation in the dentifrice advertising industry. Organized dentistry has fought these practices for years, but it is unable to cope with the problem in the absence of legal restraints and effective governmental regulating mechanisms. The situation goes from bad to worse every time a new dentifrice or a new promotional stunt is introduced. It shows no signs of abating in the foreseeable future, and as long as there is absolute freedom for the propagation of wild claims without factual support no significant change of direction should be anticipated.

5. The whole state of affairs cries out for remedy. The doctrine "Let the buyer beware" cannot be applied because the consumer is in no position to evaluate the claims. What is needed is some form of Federal action, perhaps some new legislation with teeth in it (if I may use that figure of speech) which will effectively prevent the use of inaccurate, misleading, or deceptive means to foist these dentifrice preparations upon the public. The Council on Dental Therapeutics of the American Dental Association takes the logical view that the responsibility for proving the accuracy of the claims made for the usefulness and safety of a product rests directly with the manufacturer of the product. The council does not hesitate to inform the profession when, in the council's opinion, the claims for a product are not adequately supported by the facts. As long as present Federal regulations prevail, manufacturers of highly competitive products will be encouraged to continue to outdo each other in exaggerating their claims and exploiting new but insignificant "gimmicks." The whole approach needs to be changed, in the interest of honesty and integrity in advertising, in the interest of the public welfare, and in the interest of giving 160 million consumers a fair break. We earnestly hope that this committee will recommend action toward the achievement of effective relief in this sorry situation.

Dr. PEARLMAN. In presenting this summary I shall take up the individual advertisements in the order in which they are indexed in this brochure, and for your convenience you may refer to the pictures which are reproduced in the brochure or to the enlargements that we have here for the purpose of discussion.

I want to assure you also that I would welcome interruptions for any questions you may want to raise at any time.

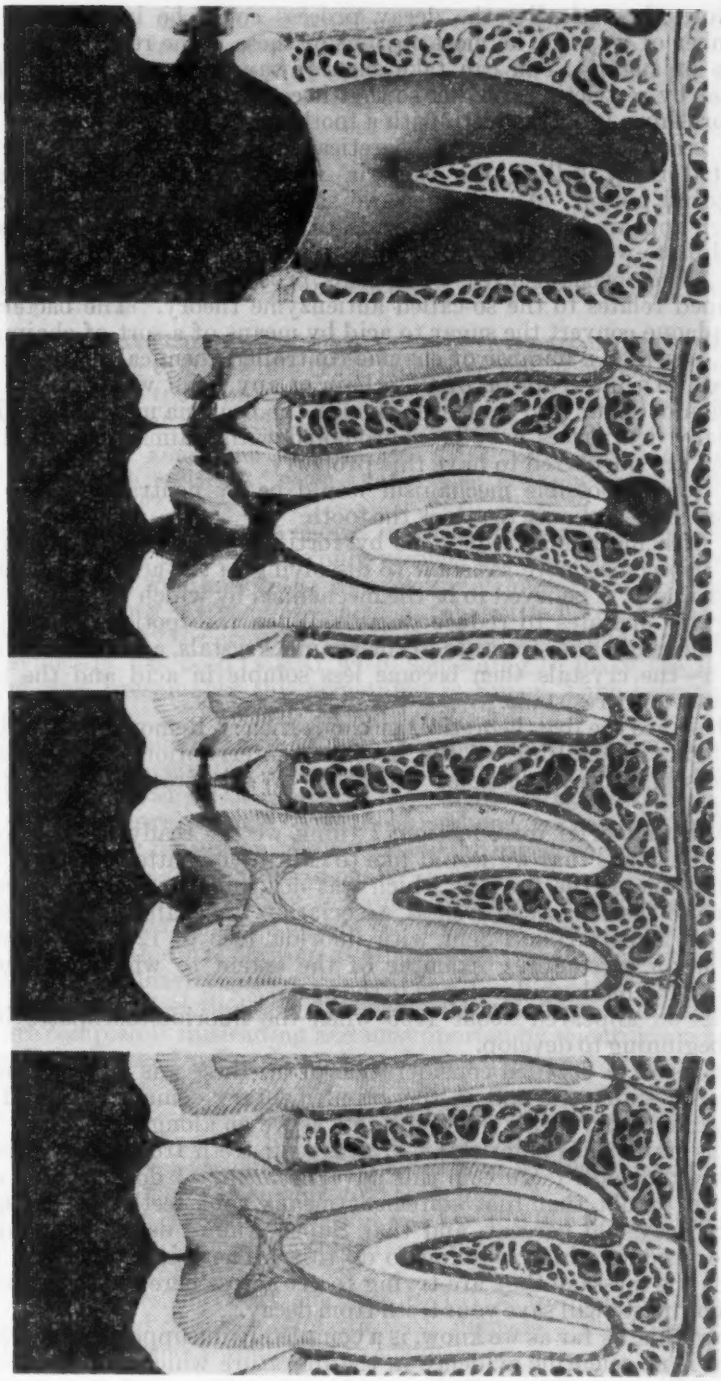
Now, as Dr. Lyons told you, the three main themes which are carried in most of these ads relate to decay-prevention claims, the idea that you can brush just once a day, and bad-breath prevention claims.

Before we can go into the decay claims, I would like to give you a capsule picture of what the decay process is, to provide background on how these claims may have been developed.

When the tooth comes into the mouth, in a very little while it is covered by what we call a dental plaque. The dental plaque is a mass of bacteria for the most part. It is a feltlike mass. It is adherent to the tooth surface, and it is preponderantly made up of bacteria which are enmeshed in a filamentous meshwork of food debris and cellular particles that are scraped from the tongue and the cheeks. These bacteria have all the facilities for converting sugars into acids and for decomposing other food residues. The entire picture of the dental decay process has not yet been elucidated, but the best authorities agree that what happens is this:

Shortly after you take sugar into the mouth in the course of a meal, the bacteria in the plaque begin to degrade this sugar very rapidly and turn it into acid, and a small amount of the acid reaches the enamel of the tooth and dissolves a little bit of the enamel.

Repetition of this procedure regularly, meal after meal and after each sweet snack, eventually results in the formation of a cavity. As Dr. Lyons has told you, this cavity then can progress from where it starts, work its way down into the tooth, becoming progressively worse, as indicated in this picture which I would like to submit also for the record, and eventually the tooth becomes infected in the pulp and is lost from the mouth.



Now, theoretically, the decay process could be interrupted in a number of ways. The most obvious of these is the removal or avoidance of sugar. You can take sugar away from the dental plaque either by restricting the diet so that it contains no sugar or sweets or by brushing it off the teeth with a toothbrush.

A second way in which, theoretically, the process could be interrupted is by killing the bacteria with some sterilizing agent or bacterial poison. And this, as we shall see, is the basis of a claim which appears in several of the ads, to the effect that ingredients in a toothpaste will kill bacteria.

A third mechanism by which this process could theoretically be stopped relates to the so-called antienzyme theory. The bacteria in the plaque convert the sugar to acid by means of a sort of chain reaction, in which a number of enzyme-controlled chemical reactions take place. An interruption of this chain at any point will stop the conversion of sugar into acid, even though the bacteria may not be killed. Many dentifrices have been promoted with claims for ingredients which are purported to have this property.

A fourth possible mechanism would be by neutralizing the acid before it has a chance to attack the tooth.

A fifth mechanism would be by fortifying the tooth somehow so that it becomes more resistant to dissolving in the acid. This latter, incidentally, is believed to be the mechanism by which the fluoridation of water operates to reduce decay. When the tooth is developing, fluoride enters the structure of the enamel crystals, and—theoretically again—the crystals then become less soluble in acid and the tooth becomes more resistant.

These are the five theoretical methods then: Removal or avoidance of sugar; the killing of the bacteria; interruption of the enzyme processes; neutralization of the acid; or fortification of the tooth itself.

With that brief introduction, I think we are ready to go into the first of the ads that we would like to call to your attention.

Now, one of the few ads which was not submitted by the subcommittee to the American Dental Association for evaluation is this one here on Super Amm-i-dent with fluoride (see p. 12). We present this as an outstanding example of the extent to which misleading advertising has been developed in the past.

This ad appeared about 1955 when the fluoride-toothpaste boom was beginning to develop.

As I said, a detailed consideration of all these ads is found in the prepared statement and in the supplementary comments, and I am just going to try to hit the highlights as we go along.

This statement [pointing] —"Saves your teeth from decay"—is obviously the main feature in this advertisement. I do not think anyone will doubt that that statement means your teeth will be saved from decay 100 percent, and that Super Amm-i-dent with fluoride is the product which is going to do this. There is no question that this is the message they are trying to get across here—that the use of the toothpaste will save your teeth from decay.

Now, this, as far as we know, is a completely unsupported statement. There is no scientific evidence in the literature which the Council on Dental Therapeutics studied—no scientific evidence whatsoever, that

any test has been made to see whether the use of Super Amm-i-dent with fluoride will indeed save teeth from decay.

Notwithstanding this lack of evidence, you will notice in the first box [pointing] the statement: "Test after test by dentists proved it." We do not know of a single test by even one dentist which would tend to prove the accuracy of this statement.

There are many other minor statements in here which I think we shall pass over. Here is one, for example, which is such an exaggeration that it will be evident to even the casual reader:

Fluoride's magic power proved! Years of research proved that fluoride—applied to enamel of teeth—saved teeth from decay, made enamel so hard cavities couldn't get started!

Before we leave this ad, I want to point to this part which I believe is an outstanding example of a trick, employed for deception. In this picture you see a tooth on the left and one on the right with a vial of something dripping on each. The heading reads:

Tests Prove Super Amm-i-dent With Fluoride Saves Teeth! Left tooth, unprotected from mouth acids * * * eaten away. Right tooth, protected by Super Amm-i-dent * * * no decay!

Now, this experiment was shown in television commercials, and it was evident from them, as it is only vaguely evident from this photograph, that this solution on the right is quite cloudy. In the case of the left tooth they say they have acid in this bottle here, and the acid has dissolved away the crown of the tooth. In the case on the right the acid evidently has been mixed with something to make the liquid opaque, and presumably this something is Super Amm-i-dent with fluoride.

Now, there is enough ammonium phosphate in Super Amm-i-dent with fluoride to neutralize a good deal of acid, and if that does not do the trick, a number of the abrasive ingredients in the toothpaste are also able to neutralize acid. So the likelihood is that this drop of liquid which is falling on the tooth on the right does not contain enough acid to dissolve a piece of chalk.

The ad is probably correct in saying the tooth was protected by Super Amm-i-dent, but it does not say that they protected the tooth by a procedure that has nothing at all to do with the manner in which a toothpaste ordinarily is used.

All in all, we feel that the statements I touched on, and others as well are completely misleading and unsupported by scientific evidence.

Mr. PLAPINGER. Dr. Pearlman, may I ask a question?

Dr. PEARLMAN. Yes.

Mr. PLAPINGER. There has been a lot of discussion in the press concerning protection to people who have been exposed to water with fluoride, and I assume this is the basis for the claim made in the advertisement. Can you comment on that, please?

Mr. PEARLMAN. If you will permit me, I would like to go to the next ad in which I will comment on this in some detail.

Mr. PLAPINGER. All right.

Dr. PEARLMAN. The next one (see p. 15) is for another fluoride toothpaste called Brisk toothpaste with fluoride. There are three points in this ad that I would like to comment on.

This top statement:

Only Brisk toothpaste gives you the same fluoride dentists use.

Secondly:

The same tooth-decay fighter proved for 10 years in drinking water.

The third statement down here [indicating statement]:

Of the many fluorides, only Brisk's fluoride is so widely used and approved by medical, dental, and public-health authorities.

It is a fact that the fluoridation of public-water supplies has been established as an effective and safe public-health measure, through much more than 10 years of sound scientific research in this field. As a result of research done on naturally fluoridated areas, fluorides in small quantities were added to water supplies in many communities, including Washington. One of the fluoride salts employed most commonly for the purpose is sodium fluoride, and sodium fluoride evidently is what is in this particular dentifrice.

Now, what this ad tries to do is tranfser the solid evidence which backs up the use of fluoride in water for the control of dental decay, to a direct application in the toothpaste, which, as far as we know, has not been tested for 10 years or even for 1 year or for any length of time whatsoever.

The statements are carefully worded so they do not actually say that Brisk toothpaste has been proved in 10 years of testing, or that dentists use Brisk toothpaste or that Brisk itself is approved by medical, dental, and public health authorities. They carefully avoid this; but the message is quite clear. The implication is that this toothpaste gives you the same effects that fluoride used by dentists will give you.

And I might make an aside here. Besides water fluoridation there is another fluoride method that is employed in the dental office. A solution of sodium fluoride is applied to the teeth of children, especially in areas where the water is not fluoridated, and will give a measure of protection against decay. This method has been established by sound research as well. In this technique dentists do use sodium fluoride, but they do not use it in the form of Brisk toothpaste.

This point in the advertisement I think, needs no more belaboring.

And this statement about approval by medical, dental, and public health authorities does perhaps apply to the use of sodium fluoride in drinking water, but it certainly does not apply to the use of Brisk.

Mr. PLAPINGER. Dr. Pearlman, what about the quantity of fluoride that is used by dentists as against the quantity in Brisk toothpaste?

Dr. PEARLMAN. You are referring to the topical application of the solution that I mentioned?

Mr. PLAPINGER. I was referring to how much fluoride there is in the dentist's application and how much there is in the Brisk toothpaste application.

Dr. PEARLMAN. I do not have exact figures on the fluoride level in Brisk toothpaste, but I would imagine it would be in the neighborhood of a tenth of 1 percent, perhaps a little more or less. The solution the dentist uses in his office is usually a 2 percent solution of fluoride, and it is applied under completely different circumstances and conditions in a manner that has been demonstrated time after time by respected scientists in the Public Health Service to give a substantial benefit in the form of decay protection.

Again, I have drawn attention only to three grossly misleading statements in the ad.

Are there any further comments?

Mr. MINSHALL. Doctor, you do not say that on this Brisk toothpaste that someone using it would not get some measure of success as a result of the fluoride in it, do you?

Dr. PEARLMAN. Perhaps I did not make that clear. We have no evidence whatsoever that that would be so. Dr. Lyons told you that brushing the teeth with a toothbrush alone will provide a measure of decay protection.

The proper thing to have done in a case like this, obviously, is: Give a group of children a toothpaste with the fluoride in it and give a control group exactly the same toothpaste but with no fluoride in it, study them carefully over a period of time, a couple of years or more, and see what difference you get due to the fluoride.

Now, this may have been done. We cannot, of course, say that it has not. We can say only that it has not appeared in the literature as far as we know. And in the material submitted to us by this subcommittee—and this material was requested from the firms, and you requested also support for these claims—there was no evidence backing up this type of claim.

Does that answer your question, sir?

Mr. MINSHALL. Well, it answers it to a degree. But if you used one-tenth percent solution or a very mild solution daily or twice daily, would that not have the same clinical effect as going to your dentist just twice a year and having him apply a 2 percent solution?

Dr. PEARLMAN. There have been studies performed, not with this toothpaste but with another toothpaste, many years ago, which contained approximately a tenth percent of sodium fluoride, and at the same time the investigators studied the use of a mouth wash containing a small amount of fluoride. This was done at a university in Boston. And in that study they found absolutely no effect which they could attribute to the use of the fluoride.

Again, we can only guess at what the exact mechanism is which gives you the benefits observed after the use of 2 percent solution in a dentist's office, and people are studying this problem intensively now.

But the solution the dentist uses is applied in concentrated form. The material is allowed to dry right on the teeth in most application techniques. And there are probably a number of factors that we still do not know about. But we do know that it works to the extent of reducing the dental decay about 40 percent on the average.

Mr. MINSHALL. How long does the application in the dental office last—the 2 percent—in the average patient?

Dr. PEARLMAN. The usual technique is to apply it for 4 minutes. And this is repeated a couple of times, depending on the stage of eruption of the teeth, so as to catch——

Mr. MINSHALL. How long does that give you protection?

Dr. PEARLMAN. This is carried on for about 3 years minimum, and repeated application will carry this through even further.

Mr. MINSHALL. You mean one application will last for 3 years?

Dr. PEARLMAN. On the average.

Mr. MINSHALL. Thank you.

Dr. PEARLMAN. This is an advertisement for Crest toothpaste (see p. 17) which is unquestionably the most widely advertised fluoride

toothpaste. Crest toothpaste is different from the other two that I have mentioned. Crest contains, instead of sodium fluoride, stannous fluoride, which is tin fluoride.

I want to call you attention only to this statement here: "Look, Mom—no cavities."

Now, this, along with the material discussed in other parts of the ad—and especially when this statement is used in the television commercials, which unfortunately I cannot show to you today—shows in effect that if you use this toothpaste you will be able to say when you come back from the dentist, "Look, Mom—no cavities," that any child who uses this toothpaste will come flying home saying, "Look, Mom—no cavities." The message is so clear in the television commercials; it is expanded upon and emphasized right through the commercials, and there cannot be any question about what they mean: No cavities. One hundred percent freedom from decay.

Now, it is to the credit of the manufacturer of this toothpaste that a great deal of research was done in developing this product. They sponsored research at independent universities and within their own plant and came up with a product which is now marketed as Crest.

Now, the American Dental Association took the initiative in this case in attempting to get cooperation from the manufacturer and discuss the claims thoroughly. As a result of negotiations, a conference was held in the association office well over a year ago, at which representatives of the scientific staff of the manufacturer met with members of the Council on Dental Therapeutics and other individuals and discussed the background for Crest toothpaste.

We reviewed the technical considerations which had to be overcome in preparing a toothpaste with stannous fluoride in it. We reviewed the earlier studies with the precursors of Crest toothpaste, the earlier forms of it, in which decay had apparently been arrested in a number of the individuals or at least there had been some reduction in dental decay.

It was pointed out that for some reason the effects were not sustained. They would get a result in the first year which might be beneficial, and after a little while, at the second examination, let's say, 2 years after the beginning of the study, the results seemed to have tapered off.

The firm tried very hard to get to the bottom of this. Stannous fluoride evidently is a relatively unstable product. It breaks down and evidently loses its effectiveness.

So, by dint of many changes in the formula, they came up with a product which at that time was marketed as Crest, and we asked them how many of these clinical studies had actually been performed with the Crest toothpaste that was then on the market. And it boiled down to the fact that only one study was in progress with the product that was marketed at that time.

Now, ordinarily, you might not think this is a serious thing. But it is a matter of common knowledge in the scientific field, particularly in the pharmaceutical field, that whenever you change one ingredient of a combination product you have to make sure that the change of that one ingredient has not altered the effects that you get. This is sometimes so sensitive a matter that even the metal or the material from which a tube or a container is made may alter the effectiveness

of a pharmaceutical agent contained in it. So the Council on Dental Therapeutics, when it evaluates products of any kind in the drug field, has always required that the experimental evidence be obtained with the product which is being promoted at the time.

We were told they had one study then in progress on the effects of Crest toothpaste. That study was performed up in Minnesota, and a report of the results of the first year has been published in the Journal of the American Dental Association. This report is submitted for examination by the subcommittee. (See appendix exhibit 1, p. 107.)

The results indicated that, after 1 year's use of a toothpaste said to be identical with Crest, the average reduction in dental caries was about 35 percent.

The study was continued, and was terminated recently at the end of a 2-year period. The results have not been published yet, but the investigators made them available to us. From this source we have information that again there seemed to be a decrease in the effectiveness of the toothpaste in reducing decay during the second year.

The decrease was so much in evidence that our analysis of the figures indicated to us that there was essentially no benefit from the toothpaste during the second year of the study.

An interesting thing—to come back to the statement that we are examining now— is that, in their original report at the end of 1 year of the study, the investigators indicated that 38 percent of the children in the group that used the Crest toothpaste had no cavities. In the control group, which used a toothpaste that did not have stannous fluoride in it, 20 percent of the children could come home and say, "Look, Mom—no cavities." But this ad does not mention that 62 percent of the children who used Crest could not come home and say, "Look, Mom—no cavities." To me, this is a clear misrepresentation of the facts.

The advertisement certainly does not adhere to the scientific findings which were developed by men of good scientific integrity and character. The ad discards their findings to the extent of making the sweeping claim that the use of Crest toothpaste will result in absolute eradication of cavities.

Mr. MINSHALL. Dr. Pearlman, may I ask a question at that point, please?

Dr. PEARLMAN. Yes.

Mr. MINSHALL. An application of fluoride by a dentist; does that give 100-percent protection?

Dr. PEARLMAN. No, sir.

Mr. MINSHALL. What percentage of protection does that give?

Dr. PEARLMAN. As I indicated to you, it gives about 40-percent protection, on the average.

Mr. MINSHALL. In other words, 60 percent will get cavities and 40 percent will not?

Dr. PEARLMAN. It is not even that good. But the point is, sir, the dental profession never has claimed that the application of fluoride in this way will do anything more than help to reduce the incidence of caries. They always have insisted on telling the patients (or telling the parents of the patient, usually) that this treatment is known to give a reduction of about 40 percent, as a rule. We cannot tell you whether your child will get this benefit. But there is a good

possibility. And it is left entirely up to the patient to say whether or not he wants to use it.

Mr. PLAPINGER. Dr. Pearlman, I notice the advertisement carries the seal of approval by Good Housekeeping magazine. Does Good Housekeeping magazine have any dental facilities, or do you know what the significance of the seal of approval is?

Dr. PEARLMAN. I cannot speak directly to that. Honestly, I do not know what facilities Good Housekeeping magazine—or Parents' Magazine, for that matter—have for evaluating these things.

The seal itself says, "Replacement or refund of money guaranteed by Good Housekeeping if not as advertised therein." Now, if this means that they have evaluated these claims, one might wonder who did the evaluation. Obviously, they missed some of the points I have been making this morning.

Mr. PLAPINGER. But the American Dental Association has had no contact on this matter with Good Housekeeping magazine.

Dr. PEARLMAN. No. At least, the council on dental therapeutics, in whose office I work, has had no request for information or no contact, as you put it, with the Good Housekeeping people.

Mr. MEADER. Dr. Pearlman, do I understand that the reduction of decay in the use of Crest toothpaste is approximately the same as the reduction in decay from application of fluoride by a dentist?

Dr. PEARLMAN. No, sir. I did not intend to give that impression.

Mr. MEADER. Well, you said 38 percent received some benefit from Crest toothpaste and about 40 percent from the dentist's application. It would sound as though they were about equivalent in reducing tooth decay.

Dr. PEARLMAN. May I clarify that? In the one case, in the case of topical application by the dentist, the tests were performed by counting the number of new lesions in the mouths of the people who got the topical application and expressing the reduction as a percentage of what the untreated cases showed.

In the case of the 38 percent of children I mentioned that could claim they had no cavities, there is an entirely different basis of evaluation. For exmaple, if there are 10 people in this room, and we count the number of cavities that all of us have, and if it turns out that there are 15 cavities in the mouths of these 10 people, the average count of cavities would be 1.5 per person. But that does not take into consideration the fact that I might have no cavities in my mouth at all, you might have no cavities in your mouth at all, and this gentleman might have 10 in his mouth. In other words, you and I could say we had absolutely no cavities. We could come home and say, "Look, Mom—no cavities."

Mr. MINSHALL. I would like to say for the record I have got about 30. [Laughter.]

Mr. MEADER. I still do not understand the distinction in the percentage. The use of the 40 percent in the case of dentist's application of fluoride and the 38 percent in the case of using Crest toothpaste. Is it the number of people who have no cavities, or the number of cavities?

Dr. PEARLMAN. The number of cavities is the case in the 40 percent figure. In the first year of the test with Crest that I was discussing, they reported 35-percent reduction in the number of cavities, in the number of new lesions, following the use of Crest toothpaste.

That 35-percent figure and the 40-percent figure are vaguely comparable in this respect.

In the second year of use of Crest toothpaste, there was no such thing as a 35-percent reduction. The figures showed there was practically no difference in the rate at which caries developed in these two groups of patients or subjects during the second year. And again I want to emphasize that, for the toothpaste, the claim is made of 100-percent protection. For the topical application procedure adopted by the association, no such extravagant claims are made.

Mr. MEADER. Now, do the scientists or the dental profession know how fluorides operate to minimize decay?

Dr. PEARLMAN. Not exactly. For that matter, sir, we do not know how penicillin works, either, but we certainly know it is useful. And in this case we know that water fluoridation certainly is effective and that the topical application of fluoride solutions to the teeth is effective to a certain extent, which we carefully delineate before applying the procedure to the treatment of patients.

Mrs. GRIFFITHS. Doctor, I was not here when you told about the control group. If you do not use Crest and you do not go to the dentist, how many of them have no cavities?

Dr. PEARLMAN. I am sorry; I misunderstood.

Mrs. GRIFFITHS. I did not understand what you said about the control group. If you do not use Crest and you do not go to the dentist, how many have no cavities?

Dr. PEARLMAN. In the control group in that study?

Mrs. GRIFFITHS. Yes.

Dr. PEARLMAN. The figure for those who used Crest was 38 percent. For those who did not use Crest, who used a control dentifrice, it was 20 percent. In other words, 20 children out of 100 had no cavities anyhow.

I think Dr. Lyons has some comment to make, and if I may interrupt my part of the testimony——

Dr. LYONS. I would simply like to add a word, if it is permissible for me to do so, because Mr. Minshall and other gentlemen of the committee have raised an important point, and I think their point bears on the difference between what this particular dentifrice vendor claims and what the profession claims.

The dental profession, as represented by the American Dental Association, has never claimed that any type of fluoride therapy will protect any one person against the disease. The profession claims only one thing: That in a group of people—as an example, ordinarily presenting 1,000 lesions in total—that if that group were treated by topical application of sodium fluoride as recommended, the total number of lesions in that group of people would be reduced by 40 percent. And if they had the benefit of fluoridated water the total number of lesions would be reduced by 60 percent or better.

But the association has never claimed that 40 percent of people or that any one person would be spared the lesions of dental caries by any type of fluoride therapy. Only the dentifrice manufacturers have claimed that they could prevent lesions in people. And I think that is a very important point of differentiation to be made.

Have I made myself clear on that point?

Mr. MEADER. I believe so, only I am not so sure I get the same meaning out of this advertisement that Dr. Pearlman does. He says

that the advertisement indicates that everybody that uses this toothpaste will be free from cavities. I am not sure that it quite says that.

Dr. PEARLMAN. In print, in actual literal fact, it does not say that. But I think it is interpreted to mean that by most readers, who do not bother to read the fine print. Certainly it is qualified here by the phrase "means far less decay." It does not say a hundred percent removal. But that phrase is in much smaller print. It does say "for grownups and children," and as far as we know, this toothpaste has never been tested on grownups. They have no idea whether it will or will not work on grownups. But they say "far less decay" here [indicating]. They say "far less new decay" in this case. And it is qualified further. "Bringing new hope" and things like that. It is qualified here and there, but the overall impression in this statement ("Look, Mom—no cavities") is certainly a hundred percent freedom from decay.

And the television commercials——

Mr. MEADER. Well, it just indicates that this boy is happy because he does not have any decay.

Dr. PEARLMAN. Quite right, sir. Quite right. In this case it does. I should like to have had the television commercials here to show you. There is no doubt from those that regardless of what the words actually say the message that is being given by showing these children running into the house waving the card—by showing shots of the experimental background for one of the toothpastes, and by the statements which are in the narrator's comments—they certainly leave no doubt in your mind that this is the message they are trying to get across.

Mr. MEADER. While I am asking questions and we have interrupted Dr. Pearlman, I would like to ask another question. I may be anticipating something. But, Dr. Pearlman, is it your contention that the Federal Trade Commission has been negligent in policing the advertising of dentifrices?

Dr. PEARLMAN. "Negligence" is a word I would not care to use.

Mr. MEADER. Well, use your own word.

Dr. PEARLMAN. All right.

Mr. MEADER. Characterize the Federal Trade Commission's activities in this field.

Dr. PEARLMAN. I would say this: That certainly something more could be done than has been done.

Mr. MEADER. That is always true, is it not?

Mr. PLAPINGER. Has anything been done, Dr. Pearlman?

Dr. PEARLMAN. Dr. Creig is going to comment on this more extensively in his part of the testimony. I think it probably would be best if that question were left to him, with your permission.

Are there any other questions you may have on these ads?

Mr. MEADER. By the way, Mr. Minshall calls my attention to one part of this advertisement. It reads as follows:

> Over a 4-year period, thousands of adults and children took part in repeated tests of Crest—the greatest "in use" testing program ever made on a toothpaste. The results, published in leading dental journals, proved that on the average, Crest means far less new decay for both grownups and children.

Now, were any results of this study published in dental journals?

Dr. PEARLMAN. If the word "Crest" were qualified in this statement by saying "took part in repeated tests of *toothpastes that were*

developed leading up to the formulation of Crest," this statement would probably be acceptable. But the point I tried to make a while ago was this: That when you change the formula, as this firm did in developing the toothpaste—when you make one change in the formula, any work preceding the use of that formula in a testing program would not qualify for consideration as adequate and conclusive evidence by scientific authorities.

Mr. MEADER. Well, then, you come to the question of whether or not the change in the formula was a substantial change or merely an improvement, a minor improvement.

Dr. PEARLMAN. Exactly so. And the way you test that, if I may interrupt you, is by working it out on the basis of effectiveness.

Mr. MEADER. Since neither the manufacturers nor the dental profession nor any scientist know the chemical operation of these fluorides in protecting teeth from decay, it is impossible to say whether the change was a material one or immaterial, is it not?

Dr. PEARLMAN. On that basis perhaps. But it is equally impossible to say that the change did not affect the effectiveness of the toothpaste.

Mr. MEADER. You are almost saying that the precursors of the present-day Crest were good but when they made improvements it was less effective, are you not?

Dr. PEARLMAN. I am not saying that. I am saying that tests were made on precursors of Crest, and those tests did show some promise of usefulness in the toothpaste tested. But for reasons that were evidenced in the course of these tests, the formula evidently required change—designed to improve it, no doubt—but every time they made a change a new test was required. Because while they were perhaps improving the stability of the active ingredient, they had to have an effective clinical trial of it before they could say that there was also improvement in the ability of the toothpaste to reduce decay.

Mr. MEADER. You are not saying that clinical trials showed that the current version of Crest is less effective than its precursors? You are just saying that there were no tests made on the current version of Crest?

Dr. PEARLMAN. The current version of Crest—I do not know whether the current version of Crest is the same as the formula that we were discussing when we met with the firm 2 years ago. They may have changed it again. But if we assume that the current formula for Crest is the same formula that we were discussing when we met with the firm, then I would say that there is only one clinical trial that we know of that has been made with this particular formula. And in that test they got no better results than they got with the preceding formulas. And during the second year there was essentially no result at all.

Mr. MEADER. I am just trying to see what the effect of your position would be. If tests were made on a product and then refinements were made to correct some instability of the compound or whatever it might be which were designed to make the product a better product and then you say they would not dare advertise that until new tests have been run every time they make an improvement in their product, is that not going to discourage research for finding improvements?

Dr. PEARLMAN. Well, I would like to examine the way you put this question to me. You say that they are making changes designed to improve the product. Now, how do they know that these changes they are making are going to make it a better product? It is only their guess, a scientific guess, that because we see this in the old product and we have changed the formula this way we should have an improved product after we make the change.

Unquestionably, laboratory tests were performed to get indirect evidence for the usefulness of the newer formula. But still the proof of the pudding is in the eating, and until you make a clinical trial you cannot tell whether your changes actually work to improve that product. And that is the point I have been trying to make.

The evidence that I have talked about from the single study in Minnesota does not indicate—to the Council on Dental Therapeutics, at least—that the newer formulation was any better than the formulas which the firm discarded——

Mr. PLAPINGER. You mean the results of the newer——

Dr. PEARLMAN. From the standpoint of improving dental health.

Mr. PLAPINGER. Did I correctly understand you to say—there were no tests involving adults?

Dr. PEARLMAN. Not with this improved formula—"improved" in quotes. The tests on adults——

Mr. PLAPINGER. The copy refers to studies on children and adults.

Dr. PEARLMAN. Yes, sir.

Mr. PLAPINGER. This is the precursor of the present formula? Is that what you are saying?

Dr. PEARLMAN. This is what I am trying to say. The tests on adults were performed with perhaps one or more of the precursors. But as far as we are aware, no adults were tested with this new formulation.

Mr. MEADER. Well, I thought you said nobody had been tested with the new formulation——

Dr. PEARLMAN. No——

Mr. MEADER. Neither children nor adults.

Dr. PEARLMAN. There is one study with children in Minnesota which I have been referring to.

Mr. MEADER. I see. I am glad you cleared that up, because I understood there had not been any testing of the new product on anyone.

Dr. PEARLMAN. I am sorry if I gave you that impression. No, there has been limited——

Mr. MEADER. In other words, the precursors were tested on both grownups and children?

Dr. PEARLMAN. That is right.

Mr. MEADER. And the new one has been tested on children?

Dr. PEARLMAN. In one study. And the results were, as I say, not very good.

The fact that the firm has gone into the testing program that it has undertaken is, I think, highly commendable, because you do not see that too often in the dentifrice field. You do not see it at all in the case of Super Amm-i-dent with fluoride. There was not a single

clinical test tried as far as we know, on that one. This firm is trying to get a good product. The firm's scientists that we spoke to would not go beyond the actual facts, but the advertisers take those facts and make this kind of statement, and that is the thing the association objects to. (See submission by makers of Crest and Gleem, appendix exhibit 2, p. 112.)

In the discussions of the last three ads we have been dealing mostly with decay-prevention claims. And actually every advertisement we are going to show here will have some claims for decay prevention. But I choose this one (indicating Gleem advertisement) to illustrate the second theme that Dr. Lyons described, namely, the encouragement of the bad practice of brushing the teeth only once a day.

This ad for Gleem toothpaste (see p. 20)—made, incidentally, by the same firm who makes Crest—says: "When you can't always brush after meals, even though it's best—start the day with Gleem."

Now, this is a frank admission that it is best to brush your teeth after every meal. This upholds the position of the association and of the best dental health authorities in the country. But—

start the day with Gleem because Gleem is the toothpaste for people who can't brush after every meal. Just one brushing destroys decay- and odor-causing bacteria.

Now, here is a direct attempt to discourage a sound dental health practice, and as far as we have been able to determine there is no evidence available which indicates that one brushing with Gleem will give you the same protection you would get from brushing your teeth after every meal. Gleem does contain a product called GL–70——

Mr. PLAPINGER. Excuse me, Dr. Pearlman. When you say "as far as you have been able to determine," what exactly does that mean?

Dr. PEARLMAN. From the literature. From the reports we read. From correspondence we had with the firm many years ago when the product first came out. And from the lack of evidence in the material submitted to us by your subcommittee staff.

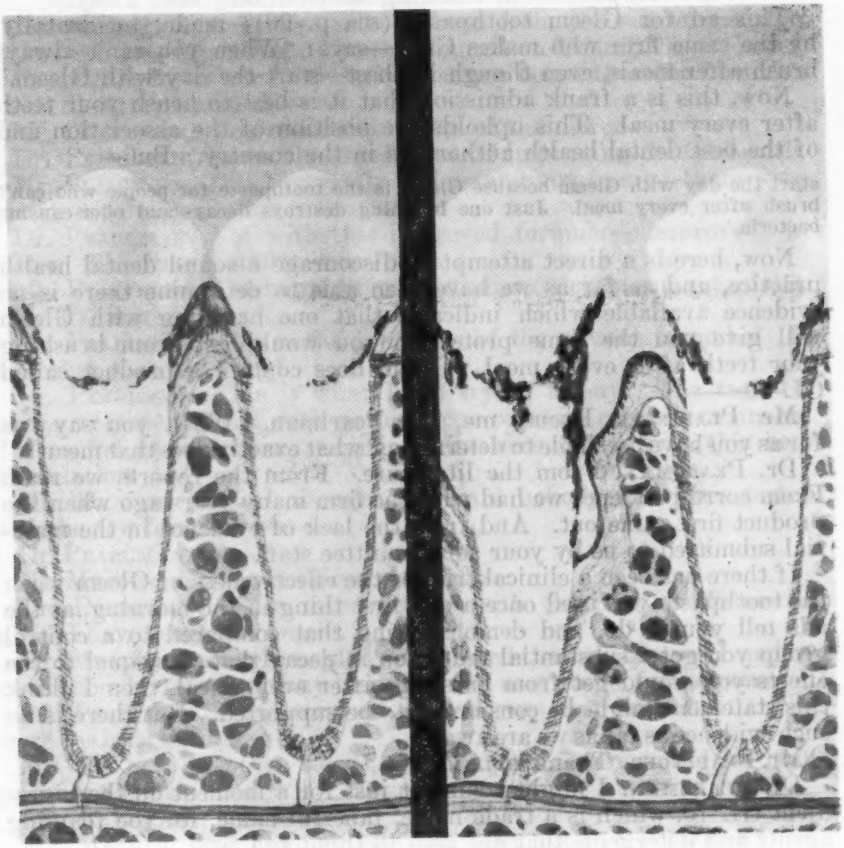
If there has been a clinical trial of the effectiveness of Gleem when the toothpaste was used once a day first thing in the morning, as the ads tell you to do, and demonstrating that compared to a control group you got a substantial reduction in decay that was equal to the effects you would get from brushing after every meal, then I think this statement might be considered to be supported. But there is no such evidence as far as we are aware.

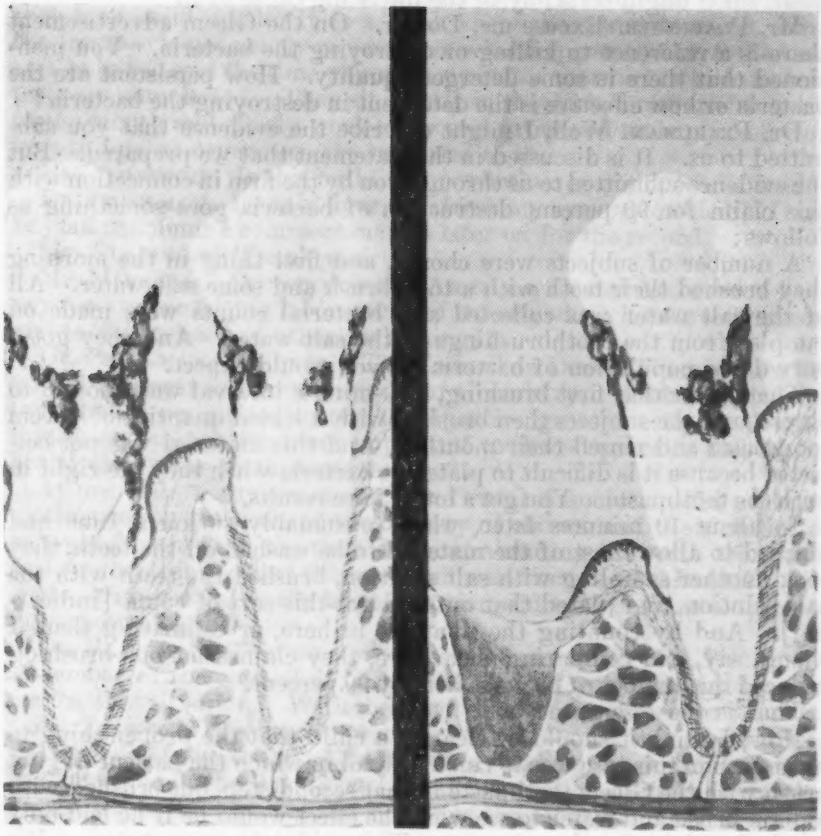
Mr. PLAPINGER. Thank you.

Dr. PEARLMAN. I might comment just for a moment on the ingredient GL–70, which is a trade name, fanciful name, for the foaming agents and detergents that are used in this toothpaste.

Now, all of the foaming agents that are used in toothpaste, even soap, do possess some antibacterial activity. But the fact that the ingredients in Gleem may kill bacteria in the test tube is certainly no direct evidence that Gleem will stop or prevent decay or reduce the rate of decay. Indirect evidence has never been acceptable to any of the scientific bodies that evaluate claims for health aids.

Do you have any questions about this one?





There is a further comment I want to make. Dr. Lyons discussed the periodontal disease problem. But this [indicating] is the progress of periodontal disease as depicted in a series of diagrams, and I will be glad to leave them with you. This is a food particle here between the teeth. If it is not brushed away, tartar deposits will form near it. The tissue shows an inflammatory reaction and backs away from it. A pyorrhea pocket forms next to the tooth. The gum tissue recedes. The bone begins to be destroyed. The tooth begins to lose its support from the surrounding bone. And eventually the tooth is lost. And this is all because this particle was not removed after every meal, for it might certainly be the initiating cause of it.

Mr. PLAPINGER. Excuse me, Doctor. On the Gleem advertisement there is a reference to killing or destroying the bacteria. You mentioned that there is some detergent quality. How persistent are the bacteria or how effective is the detergent in destroying the bacteria?

Dr. PEARLMAN. Well, I might describe the evidence that you submitted to us. It is discussed in the statement that we prepared. But the evidence submitted to us through you by the firm in connection with this claim for 90 percent destruction of bacteria goes something as follows:

A number of subjects were chosen, and first thing in the morning they brushed their teeth with a toothbrush and some salt water. All of the salt water was collected and bacterial counts were made on samples from the toothbrushings in the salt water. And they got a very dense population of bacteria, as you would expect.

Then, after that first brushing, a 10-minute interval was allowed to elapse, and the subjects then brushed with a stated quantity of Gleem toothpaste and rinsed their mouths. And this material was not collected because it is difficult to plate out bacteria when they are right in with the toothpaste. You get a lot of false results.

So about 10 minutes later, when presumably sufficient time had elapsed to allow most of the material to be washed off the teeth, they took another sampling with salt solution, brushed the teeth with the salt solution, and plated that out and got this sort of count [indicating]. And by counting the numbers in here, or estimating them I should say, and comparing them here, they claim that one brushing reduced the number of bacteria here by 90 percent.

That is the essence of it.

Now, I think it should be clear to a child that the proper thing to have done in this case was to run a control in which the patient did not brush with the Gleem toothpaste in that second step, but brushed with a plain brush and water to see what the effect would be if he had only brushed with his brush and water. This evidently was not done. We do not know whether that in itself might not reduce the bacterial count in those specimens by 90 percent.

But the more important thing is this: This kind of test tells us the number of bacteria that could be dislodged and tells us what happens to them when Gleem is used in between. It does not tell us what happens to the bacteria that are still in the plaque which adheres very firmly to the teeth in the pits and fissures where dental decay starts—and in between the teeth in the interproximal areas. It tells us nothing about what Gleem or other toothpastes or brushing itself has done to inhibit the activity of those bacteria. This tells us only what we can find about bacteria which are readily removed from the teeth.

Mr. JOHNSON. The implication in the Gleem advertising is persistence of protection—that is, one brushing gives protection all day. What would the situation be with respect to this bacterial count say 8 hours after the brushing with Gleem?

Dr. PEARLMAN. As I recall, sir, and the direct evidence is to be submitted for the record, there was a tapering off. There always is this effect. When you brush your teeth in the morning you remove most of the bacteria that have piled up around the teeth during the night. I think every one of us knows how his teeth feel first thing in the morning. The film is gone with the first brushing. From that time on the bacteria, through use of food and so forth, are kept down. Gradually they may build up slowly to a level where the count increases. But the increase is not nearly so severe as what happens between the time you go to bed and the time you wake up in the morning, while the bacteria are unmolested. They sit quietly in the dark, moist environment of the mouth and slowly work away and grow and multiply and convert things, as organisms are supposed to do.

Mr. PLAPINGER. Is this building up whether or not Gleem is used?

Dr. PEARLMAN. I would have to refresh my memory on that. I will be glad to submit a comment on this later on for the record.

Mr. PLAPINGER. Thank you.

Mr. MINSHALL. Doctor, does the American Dental Association have any research or testing laboratories of its own where it tests toothpastes and toothbrushes and other such things?

Dr. PEARLMAN. We have. The Council on Dental Therapeutics has within its organization a Division of Chemistry. We have a laboratory that is designated to test therapeutic agents, mostly local anesthetics and things far more important to dental practice and dental health than these toothpastes seem to be.

At one time, many years ago, the Dental Association did evaluate toothpastes on the basis of the honesty of claims, and their ability to help the brush clean the teeth without abrading the teeth too much, and similar things. But this program was discontinued in 1947.

Mr. MINSHALL. On the basis that you did not consider toothpaste important enough?

Dr. PEARLMAN. This was only a part of our work. Dr. Lyons was a member of the council at that time. Would you like him to summarize that situation? With the permission of the chairman?

Dr. LYONS. Well, there were many reasons for the council dropping its detailed consideration of dentifrices—one being its inability within the resources of the American Dental Assocaition to make an impact on the public because we did not have the money and the means to reach the public with the means that were available to us. And, in addition, because dentifrices are categorized as comestics rather than drugs, the council felt that with its limited resources it could devote its time to better advantage in the interests of the profession and the public by devoting its activities to drugs rather than comestics.

It did have and continues to keep an eye on therapeutic claims for these comestic agents with a hope that some day a truly therapeutic dentifrice may be found. But in the meantime it keeps an eye on them to evaluate claims which up to this point have not been fully substantiated.

Dr. Pearlman, may I add to your fine statement on the question of bacterial count? I know this is intruding in your bailiwick, but I think that is so important.

There is a total bacterial count of the mouth which no one has yet established for any mouth. There is a count that may be made of the expellable bacteria. There is no known means of establishing the count for the residual bacteria of the mouth, those that cannot be expelled.

Now, the reduction in bacterial counts to which reference is made is a reduction in the bacteria that may be expelled, not those that are retained.

Now, of the two groups of bacteria, the less significant are those that may be expelled. The more significant are the bacteria that are retained in the pits and fissures and crevices of the teeth, in the folds of the mucous membrane between the cells of the mucous membrane and the covering of the tongue and in the gingiva around the teeth. We have no means of establishing a count of bacteria in these areas and no means of determining whether Gleem or a mouthwash may affect this number. But an educated guess is that the bacterial count referred to as the residual count is affected little if at all by the use of a dentifrice, from its chemical point of view, or a mouthwash. And I think that is a very important consideration.

Now, in connection with a hearing before the Federal Trade Commission I believe in the late thirties, in a hearing dealing with a popular mouthwash, it was established that—by the use of this mouthwash and by the method described by Dr. Pearlman—that the expellable bacterial count could be reduced I think somewhere in the range of 95 percent. But the firm did not say that you could reduce the count by brush and water also in the range of 90 percent by doing what the American Dental Association recommends that everyone practice, and that is: the frequent and regular use of the brush with or without a dentifrice to remove residual food particles and other substances around teeth which promote the growth of bacteria.

Mr. MINSHALL. Doctor, I want to get this point cleared up if I may about this testing of toothpaste. Do you know of any independent research or consumer testing laboratories that have conducted any tests of all toothpastes?

Dr. LYONS. The American Dental Association some years ago tested toothpastes from the standpoint of their comparative and relative abrasiveness—that is, with reference to the injuries that some dentifrices up until that time were known to create in teeth. And I might say that the work of the American Dental Association and others in that field was responsible for improvement in the physical qualities and the abrasive ingredients of dentifrices to the point where they are now, relatively speaking, safe to use as prescribed and no longer contain abrasives so dangerous to use with reference to destroying the enamel.

Mr. MINSHALL. My question is, Doctor, do you have any knowledge of any independent research or testing laboratories making any such tests?

Dr. LYONS. No.

Mr. MINSHALL. Is there any question in your mind about current dentifrices possessing any dangerous qualities?

Dr. LYONS. I did not quite get that.

Mr. MINSHALL. Let me ask that question again then. Is there any doubt in your mind that some of these presently advertised dentifrices that we are discussing here today have any dangerous qualities, harmful qualities?

Dr. LYONS. There is doubt, yes.

Mr. MINSHALL. If there is doubt, then let me ask this: Why, rather than just consider them as cosmetics, does not the American Dental Association conduct some tests in the interests of medical or dental associations?

Dr. LYONS. Well, let me answer that in just a moment. But first let me refer back to your other question. Independent research workers have carried on studies on dentifrices. Dr. Thomas J. Hill at Western Reserve University for one has carried out extensive studies.

Mr. MINSHALL. Have they been published?

Dr. LYONS. Yes, they have been published.

Mr. MINSHALL. Where have they been published?

Dr. LYONS. In the Journal of Dental Research. Thomas J. Hill at Western Reserve.

Mr. MINSHALL. How recently were those published and when were those tests made?

Dr. LYONS. Oh, I do not know exactly. Within the past—what?—5, 6, 7 years?

Dr. PEARLMAN. Yes. These are clinical trials.

Mr. MINSHALL. Nothing to do with the fluorides or some of these other chemicals though they are putting in the present-day dentifrices?

Dr. LYONS. Yes, he has made studies on fluoride-containing dentifrices, and also on penicillin-containing dentifrices.

Mr. MINSHALL. Are those results going to be made available here to this committee?

Dr. LYON. They can be.

Mr. MINSHALL. Mr. Chairman, I think it would be interesting to have those if it is possible, if they are not too voluminous.

Dr. LYONS. The reports appeared in the journal.

Mr. BLATNIK. If they appeared in the journal, we will get them and we will include them in our file.

Dr. LYONS. Now, with reference to Mr. Minshall's question about doubt concerning the safety of dentifrices, when the Food and Drug Administration held a hearing on whether or not fluoride-containing dentifrices might be marketed over the counter, the dental interests, professional interests, were present to help the Food and Drug Administration in evaluating such things as whether or not if a child ate an entire tube of toothpaste he might be hurt by it. That is evidence of concern as to whether or not dentifrices are safe to use.

Mr. MINSHALL. Is there any doubt about any of these toothpastes that we have brought out here by name today, some of these more prominent ones such as Crest, Gleem, Ipana, Colgate, Pepsodent, Stripe? Is there any inherent danger or harmful effect in those toothpastes?

Dr. LYONS. In the substance itself, no. In the misleading advertising, yes.

Mr. MINSHALL. That is all I have.

Dr. PEARLMAN. This is another example of advertising which misleads concerning the effectiveness of toothpaste in reducing decay.

This is an ad for Ipana toothpaste made by Bristol-Myers. (See appendix, exhibit 3, p. 162.)

The main slogan here (see p. 24) is: "This space reserved for a tooth that must last for 63 years." It clearly indicates that the message there is: If you use Ipana toothpaste your teeth will last you a lifetime. There is no evidence—and I am not speaking of evidence on people who have used Ipana for a whole lifetime—there is no evidence even from short-term studies as far as we are aware that have ever been conducted to show Ipana toothpaste will substantially reduce dental decay.

The ad refers to "WD–9," one of the ingredients of Ipana, which is their trade name for another foaming agent—sodium lauryl sulfate, I believe. And, as I pointed out, most of the foaming agents that are employed in toothpastes and elsewhere do have antibacterial activity.

In an ad which is a companion to this one and which I may have a word to say about later, there is a statement that Ipana with WD–9 actually has twice the decay germ killing power of any other leading toothpaste.

Now, these tests were performed in a laboratory, and there is a technique which is described in fair detail in the material submitted to the committee and which you asked us to review. Essentially, they tried to show in these tests on the use of Ipana toothpaste that a pledget of Ipana on a bacteriological plate produced a certain zone of inhibition and that this zone of inhibition was always twice as big as the zone of inhibition produced by unidentified brands of "popular toothpastes." The other toothpastes, as I said, were unidentified. In each of the series of tests done on different days on different groups and in different weeks, perhaps Ipana did appear to show up much better than the others. But if you look at the results they got for Ipana alone in the different tests, you find the zone is 2 millimeters wide this time, 8.3 millimeters wide another time, and 7 to 15 millimeters wide at other times. There was variation 4 to 8 times in the so-called standardized test itself, so that the validity of he comparative studies does not hold up. If the standard you are measuring these other toothpastes against varies fourfold to eightfold, what good are results which illustrate only a twofold improvement or a twofold superiority over other products? So far as we are concerned, we would not give this claim any consideration at all as a "substantiated claim."

The comments on bad breath are covered extensively in the prepared statement. I would like to leave this. The important thing about the bad breath situation and the claims has been covered by Dr. Lyons. It is a hazard that is related to masking the disease situation, like using perfume when you really need a bath, and it doesn't do you any good. [Laughter.]

Now, this ad is for the toothpaste which unquestionably outsells and has outsold every other brand of toothpaste, and will for some years to come. This is Colgate's dental cream with Gardol. (See p. 26; see also appendix exhibit 6, p. 172.) Dr. Hess is prepared to give some testimony in connection with the effectiveness of Gardol itself, but I want to call attention to this shield here [indicating], the Gardol shield. And I call attention to it only because it is a miniature replica of the tremendous invisible barrier that you see in the television commercials, if you have time to watch them. In these

commercials—and they have become even more elaborate during the past few months—you see such things as this: A man is standing near some palm trees and in the distance somebody is throwing coconuts. And all of a sudden a coconut is seen flying toward the man's head. But he doesn't move because the invisible barrier deflects the coconut. Then he says: "Just as this invisible barrier"—and he knocks in the air, a solid sound—"protects us against this thrown missile, so does Gardol protect your teeth against decay."

Well, to say this is an exaggeration of the facts, I believe, is an understatement if ever one was made. I am not sure what evidence they have to indicate that just one brushing with Gardol will form an invisible protective shield around your teeth that fights tooth decay all day. My guess would be that tests are performed after the use of Gardol to see how long the ingredient is retained on the surface of the teeth. Now, you can get chemical tests that pick up trace amounts of this material probably 12 hours after you use it, but does that mean the shield is covering each one of your teeth effectively and protecting it against decay and bad breath germs, and so forth, for that length of time? The likelihood is no.

First of all, that shield is likely to be shot full of holes from the use of food and from other things we do with our teeth during the course of the day and diluted away by saliva and fluids which we drink. And, although the test at the end of the day may still detect small amounts of the material, the evidence of a protective shield certainly is no longer there, even if it was there in the first place.

Mr. MINSHALL. Dr. Pearlman, this question has been asked previously, though not exactly the same way. The guaranty by Good Housekeeping seal is on that ad. Have you ever made inquiry to Good Housekeeping as to whether or not they make independent tests of these advertised products?

Dr. PEARLMAN. I have not done so, sir.

Mr. MINSHALL. Mr. Chairman, I think it would be wise if this committee made a request of the Good Housekeeping magazine to state just upon what basis they make available that seal they put on there.

Mr. BLATNIK. We will make the inquiry.

Mr. MINSHALL. Thank you, sir.

(See appendix exhibit 4, p. 169.)

Dr. PEARLMAN. On that point, I can only say that, as far as we know, we have had no contact with the Good Housekeeping staff or the staff of Parents' Magazine, which also displays the seal of approval, which might indicate they are interested in our opinion of these products as they come out. Whether or not they have dental scientists on the evaluating staff, I am not able to determine.

Mr. MINSHALL. Consumers Research and other magazines; do they ever test these things? They test cigarettes and everything else.

Dr. PEARLMAN. Consumers Reports has on occasion carried articles on the abrasiveness and effectiveness of dentifrices in cleansing teeth.

Mr. MINSHALL. I asked that question earlier, and you said that no tests had been made by other private testing groups.

Dr. PEARLMAN. Did you ask that question of Dr. Lyons?

Mr. MINSHALL. I asked the question generally.

Dr. PEARLMAN. This couldn't be categorically. Other testing groups have——

Mr. MINSHALL. What are those?

Dr. PEARLMAN. The group I'm speaking of now—Consumers Union, which publishes Consumers Reports—they have access to a machine which tests abrasiveness and polishing effects, and so forth. On occasion, unquestionably, professional testing companies will run abrasive tests on a product if they are asked by a manufacturer to do so. But this responsibility, sir, appears to be one which the manufacturer should take over. The American Dental Association is concerned with health claims as well as safety claims. We no longer do this abrasive testing in our laboratory. I thought, sir, you were referring to the clinical testing of these dentifrices.

Mr. MINSHALL. Any testing of dental——

Dr. PEARLMAN. This clinical testing of effectiveness—when you take several hundred children and give them a control toothpaste and an experimental toothpaste and see what effect you are going to get—this is something the association couldn't possibly undertake because of the expense involved. But each manufacturer should be obligated to perform these tests on his product before he promotes them to the public. The public can't evaluate them otherwise, nor can the profession.

Mr. MINSHALL. What health claim does this particular Colgate ad have, aside from bad breath?

Dr. PEARLMAN. "Colgate's fights tooth decay all day—with just one brushing [indicating]." "Colgate's contains Gardol to form an invisible, protective shield around your tooth that fights tooth decay with just one brushing." If that isn't a therapeutic claim, I'm afraid I can't recognize one.

Mr. PLAPINGER. And the point there is that, while the detergents may inhibit the bacterial activity, I believe you say in your statement, it is not the same thing as the ability to prevent cavities from forming?

Dr. PEARLMAN. That's right. At this point, I would like to ask Dr. Hess, with your permission, Mr. Chairman, to testify about some of the work that has been done with the ingredient, Gardol, which is sodium N–lauroyl sarcosinate. In that connection, I would like to mention that this ad says only Colgate's contains Gardol, and so forth; it says: "And of all leading toothpastes"—asterisk—"only Colgate's contains Gardol to form an invisible, protective shield," and so forth. You look for the asterisk down below and the asterisk refers to "Top three brands after Colgate's"—in microscopic print. This is, obviously, a gimmick to get around stating the fact quite clearly. It is a fact that a number of lesser known toothpastes contain sodium N-lauroylsarcosinate. Walgreen's is one, Sears, Roebuck's is another. Evidently Super Ammi-dent with fluoride is another that contains sodium N-lauroyl sarcosinate. I'd like to stop here, as I said and ask for Dr. Hess to take over, after which there are a couple more ads I'd like to discuss.

Mr. PLAPINGER. What is the other toothpaste you referred to with this same substance?

Dr. PEARLMAN. Super Amm-i-dent with fluoride.

STATEMENT OF DR. WALTER C. HESS, ASSISTANT DEAN AND PROFESSOR OF BIOLOGICAL CHEMISTRY, GEORGETOWN UNIVERSITY SCHOOLS OF MEDICINE AND DENTISTRY

Dr. HESS. How much time do we have, Mr. Chairman?

Mr. BLATNIK. If you could just summarize it, because the House goes into session at 12. There is an important session this afternoon. We expect a rollcall shortly after 12.

Dr. HESS. I will cut it down to just about a minute. Most of my remarks are in the prepared statement, anyway. For the information of the committee, I am a biochemist, and not a dentist. And we have approached just one problem and that is: Does the Gardol prevent the formation of acid, which is the activity of an antienzyme substance? This is a problem that can be tackled in the lab, since all we are doing is measuring the degree of acidity on a tooth. And, as a result of the study on the teeth of a number of individuals, a report is in the literature from one of our leading schools to the effect that Gardol does reduce the formation of acid on the tooth. Our experiments are to the contrary. Our findings were that it does not. So you might say it is 1 against 1. However, another independent laboratory at one of the leading dental schools in the country, referred to in the statement, made a similar test, and their experiments agreed with ours—that Gardol did not produce any reduction in the degree of acidity.

Now, the same individual who published the article on the acid formation also conducted a clinical study. The leading member of the group, like myself, was a biochemist. Their study is a little difficult to evaluate because there were 4 different groups in 4 different cities, but about the best that you can make out of it is that the control group—and these are just numbers—there was a starting variation between 16 and 19.7 in the control and 16 and 19 even in their test group. After 2 years, the control group varied between 16.4 and 20.5. The experimental group varied between 16.2 and 19.4. So you see there is no great change in the upper and lower limit between the control and the experimental group.

If you just take the upper limit, the most cavities that were formed, you will find a difference in 1 case of 8 parts in 200, and in the other of 4 parts in 200. So at the most you can say a 4-percent difference favoring the control group. And certainly that is not a substantial reduction in decay. It certainly is not stopping decay. You might make the comparison that, if you are relying upon a brake in your automobile, you are not interested, if you are going 20 miles an hour, whether it will cut it down to 19. You want to stop your car. That's all I have to say, gentlemen.

(The prepared statement of Dr. Hess is as follows:)

STATEMENT OF DR. WALTER C. HESS, ASSISTANT DEAN AND PROFESSOR OF BIOLOGICAL CHEMISTRY, GEORGETOWN UNIVERSITY SCHOOLS OF MEDICINE AND DENTISTRY

DISCUSSION OF CLAIMS FOR GARDOL

My name is Walter C. Hess. I am assistant dean and professor of biological chemistry at Georgetown University Schools of Medicine and Dentistry. I received my bachelor of science degree (in chemistry) from the University of Pennsylvania in 1920, and also received a doctor of philosophy degree in biological chemistry in 1930. I have been in the field of biological chemistry for over 30 years and have written almost 200 papers describing research in which I have been engaged. My field of specialization is nutrition and protein chemistry and part of my research has been directed toward the biochemistry of tooth structure, particularly the protein components.

I have always been an experimental scientist and not a clinician. My approach to problems concerned with teeth and their composition has been that of a laboratory worker. I have tried to apply the standard techniques of the protein chemist to obtain information concerning the structure of realthy and carious teeth. The clinicians, the dentists in our school clinics, tell me which teeth are healthy and which are carious, and I follow their guidance.

It would be worthwhile to have a laboratory test that could be used to tell the clinician when and if a person is going to develop dental caries. It would be equally desirable to have a laboratory test that could tell the clinician whether some substance that has been applied to a tooth is going to protect it against the future development of caries. One approach to these problems has been based upon the concept that caries results from the action of acid upon the tooth structure. The chemist can measure acid; he has very sensitive methods that can detect minute changes in acid concentration. These measurements can be done in saliva and they can even be done right on the surface of the tooth. We have instruments that can be applied to any part of the tooth in the mouth of the patient.

The usual source of the acid that is formed is the fermentation of sugar by micro-organisms on the surface of the tooth. If one prepares a solution of sugar and simply holds some of it in the mouth for a minute and then spits it out, a film of the sugar solution is deposited on the teeth. If the degree of acidity of a tooth surface is measured before and after such a sugar rinse, the changes can be observed. In most individuals the sugar produces an increase in acid, an increase that persists for about 10 minutes.

One logical approach to the problem of caries control would be to apply something to the surface of the teeth that would prevent the fermentation of the sugar. Such a substance could be incorporated into a toothpaste and simply brushing the teeth would confer immunity.

About 5 years ago an article appeared in the Journal of Dental Research describing a search for such a substance.[1] The test employed was the one I described—each substance was examined to determine whether it would prevent the fermentation of sugar. Several substances looked promising; one of these, sodium N-lauroyl sarcosinate, bearing the trade name of Gardol, was subjected to a series of toothpaste tests. These tests, according to Dr. Fosdick, the senior author of the article, indicated that Gardol prevented the formation of acid on the surface of the tooth.

Dr. B. K. Forscher and I repeated these experiments; we purchased Colgate's Gardol toothpaste in the open market, and used dental students as our subjects. We divided them into two groups; one group received the Gardol-containing toothpaste in tubes with only a distinguishing letter. The control group received a toothpaste containing no Gardol. The students were unaware of the nature of the toothpaste. The laboratory worker knew the students by name only, and had no knowledge whether the student was brushing with the Gardol-containing toothpaste or the control. The study was therefore a "double-blind" investigation, in which subjective influences were kept to a minimum. When the student came to the laboratory, the acidity of the surfaces of several teeth was measured; then he was given a fixed amount of sugar solution. After 1 minute

[1] Fosdick, L. S.; Caleandra, J. C.; Blackwell, R. Q., and Burrill, J. H. New Approach to the Problem of Dental Caries Control. J. D. Res. 32: 486 August 1953.

the sugar solution was expectorated and acidity was measured. Two more measurements were made—at the end of 5 and 10 minutes.

After the students had been brushing their teeth with the respective toothpastes for several weeks and considerable data had been accumulated, the results were tabulated against the concealed information on the distribution of the two toothpastes. No differences were found between the two groups of students; acid was formed in both cases. These results, in direct contradiction to those of Dr. Fosdick, were published in the Journal of the American Dental Association.[2]

Here, then, were two publications—one saying that Gardol prevents acid formation on the tooth surface, and the other saying it does not. What is needed in such a case is a third independent assay, such as provided by Dr. Brudevold of Rochester,[3] and it in essence confirmed our finding. No rebuttal of the two "contra" papers has ever appeared. This has never had the slightest effect upon the Colgate advertising campaign. Gardol is still the magic shield that protects against the insidious onslaught of acid. Apparently, the advertisers ignore any scientific evidence which does not support or which challenges the thesis of their sales pitch.

The experiments I have been describing all are capable of being performed in any biochemical laboratory. Dr. Fosdick is not a dentist, and you would not expect him to furnish clinical evidence in support of Gardol. Yet in the journal Science, he offers clinical evidence purporting to show that the use of a toothpaste containing Gardol effectively prevents decay.[4] I am not a dentist either but I am qualified to examine and evaluate clinical data. I have never examined the teeth of the test subjects, but Dr. Fosdick hasn't looked at them either. We are both just examining recorded figures.

In Dr. Fosdick's study, several groups of subjects were employed, living in different parts of the country. In the report these sub-groups are designated as Gainesville, Miami, Meredith, and Drake. They were examined by different examiners, and the health of their teeth was assayed; a numerical value can be obtained by counting the number of teeth that are decayed, missing, or filled. In this study the investigators recorded decayed, missing, and filled tooth surfaces (DMF surfaces) and decayed or filled teeth (DF teeth) as units for measurement.

After the baseline examination, the several groups then used Gardol toothpaste either once or twice a day, and control groups did the same thing with non-Gardol-containing toothpastes. Dental examination 1 and 2 years later indicated new numerical DMF and DFT values of the dental health of the patient. A larger value at the later date means a deterioration of dental health during the period. All groups of the patients, whether they used Gardol or not, had larger numbers on the second examination. Evidently Gardol did not build an impenetrable shield against tooth decay.

The statistics showed that some reduction occurred in the appearance of new decay in the groups that used the Gardol toothpaste, as compared with the control groups. The net average increase in DF teeth over the 2-year period for the Gardol groups is shown as 0.22 DFT units, or 22 new decayed or filled teeth per 100 patients. For the control groups the average increase was 0.47 DF teeth, or 47 new DF units per 100. But the variation in the amount of caries within the control groups and within the test groups was several times greater than this apparent change induced by Gardol.

For example, at the first examination the DFT values in the control groups (designated group C–2–D in the report) varied from 16.0 in the Meredith subgroup to 19.7 in the Gainesville subgroup, a difference of 3.7 units or 370 DF teeth per 100. After 2 years the range was from 16.39 to 20.46, a difference of 4.07, or 407 DF teeth per hundred.

In the experimental groups (designated collectively as T–1–D), the initial DFT ranged from 16.0 to 19.0, a difference of 3.0 DFT units; after 2 years the range was from 16.18 to 19.4, a variation of 3.22 DFT units.

The decay reduction claimed on the basis of the average figures of 0.47 DFT and 0.22 DFT is 53 percent, based on the difference of 0.25 DFT units. But a claimed reduction of 0.25 units, if not absolutely meaningless, is certainly open

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[2] Forscher, B. K., and Hess, W. C. Validity of Plaque pH Measurements as a Method of Evaluating Therapeutic Agents. J. A. D. A. 48: 134 February 1954.

[3] Brudevold, Finn; Little, Marguerite, and Rowley, Janet. A Study of the Acid-Reducing Effect of "Antienzymes" in the Mouth. J. A. D. A. 50: 18 January 1955.

[4] Fosdick, L. S. Clinical Experiment On the Use of Sodium N-lauroyl Sarcosinate in the Control of Dental Caries. Science 123: 988 June 1, 1956.

to serious question in the face of internal variations of the order of 3.0 or more units within the groups themselves. The variation within the groups was as much as 12 times as great as the 0.25 unit difference that was claimed. Obviously there was something wrong with the methods employed for measurement of the effects.

By comparison, for the purpose of illustration, you might think of how accurately you could measure differences in the size of two pinheads if your ruler was a yardstick crudely marked off in eighths of an inch. Your baseline markings would be many times larger than the differences you were trying to measure, just as the baseline variations within these subgroups were many times larger than the difference in decay rates which these investigators were trying to measure.

These are some of the major inadequacies of the Gardol toothpaste investigation. They are more than sufficient to cast doubt on the significance claimed for the results. In situations like this, it is essential to have confirmatory evidence from independent studies. No confirmation or clarification of these clinical results appears in the literature.

It is interesting also to compare the results obtained in the subjects who brushed their teeth once a day with those who brushed twice a day. Previously Dr. Fosdick had reported that merely brushing the teeth twice a day, with an ordinary toothpaste, reduced the amount of caries.[5] In these Gardol studies, however, it made no difference whether the teeth were brushed once or twice a day; the same numerical values were obtained.

It is apparent that the advertising claims for protection against acid formation by Gardol are not supported by published data. In fact, the published data states just the contrary—2 to 1. The general public is in no position to distinguish between proven and unproven claims and needs some protection against claims that are demonstrably unfounded.

Mr. BLATNIK. Thank you, sir.

Dr. Pearlman, do you want to continue now?

FURTHER STATEMENT OF DR. SHOLOM PEARLMAN, ASSISTANT SECRETARY, COUNCIL ON DENTAL THERAPEUTICS, AMERICAN DENTAL ASSOCIATION

Dr. PEARLMAN. Mr. Chairman, the other two ads we have up there are displayed here in the booklet and they are discussed in some detail in this prepared statement (see pp. 30–32). So with your permission, I would like simply to summarize the basic issues that I have been trying to present here.

Mr. BLATNIK. Please proceed.

Dr. PEARLMAN. The primary purpose of a dentifrice is to assist the toothbrush in cleaning the teeth. The cleansing process of brushing, with or without a dentifrice, removes potentially harmful food residues, and reduces the opportunity for acid formation which is an important factor in causing tooth decay. Regular brushing also is advocated for the prevention of gingivitis and periodontal disease, and for the maintenance of hygienic conditions in the mouth.

Adequate scientific evidence has not yet been produced in support of the special decay-preventive claims that are made for nationally advertised dentifrices. The presence of various additives in these products has not been demonstrated to produce the effects ascribed to them in the promotional material.

The advertisements for most of the major dentifrices are grossly deceptive and misleading. Through the use of half-truths, pseudoscientific statements, and distorted implications, they tend to create

[5] Fosdick, L. S. The Reduction of the Incidence of Dental Caries. I. Immediate Toothbrushing With a Neutral Dentifrice. J. A. D. A. 40: 133 Feb. 1950.

a false sense of security about dental health. This is harmful because it leads people to neglect sound health habits. In some cases the advertisements openly advocate disregard for the frequently essential practice of brushing the teeth after each meal.

This essentially is our position. I believe Dr. Creig is now prepared to continue with his part of the testimony.

Dr. CREIG. Do you have time, Mr. Chairman, for our conclusion, which is short?

Mr. BLATNIK. Yes, we will continue until we hear the quorum bells. Will you please identify yourself for the record?

FURTHER STATEMENT OF DR. RALPH E. CREIG, CLEVELAND, OHIO; MEMBER, COUNCIL ON LEGISLATION, AMERICAN DENTAL ASSOCIATION

Dr. CREIG. I am Dr. Ralph Creig of Cleveland, Ohio, and a member of the American Dental Association's council on legislation.

It seems obvious that only the Federal Government has the resources effectively to control misleading and deceptive claims for nationally advertised products. It seems equally obvious that with respect to therapeutic claims for dentifrices and, it might be observed, for a variety of proprietary nostrums, such control is either woefully inadequate or nonexistent.

One has only to glance at the commercials on television or in the pages of any newspaper or magazine to find the pitchmen touting their wares—from toothpaste to headache pills—in such glowing terms that, if only half of what they say is true, we all can go through life serenely, healthfully, without discomfort of any kind, simply by purchasing a tube of toothpaste, a package of pills, and a bottle of tonic. This propaganda, reeking with high-sounding but meaningless scientific terms and formulas, carefully hedged to skirt the law, and designed to entrap the hopeful but unwary consumer, floods the airwaves and gluts the printed page. It is distinguishable from the harangue of the old-time medicine show only in that the approach is more subtle and the audience more vast.

It is regrettable but understandable that advertising of this type is successful. It is successful because it preys upon the age-old desire of human beings to find the permanent panacea for pain and disease. And it is successful to the tune of millions upon millions of dollars a year.

Something should be done about these abuses. The public is not well enough informed to protect itself. This is pathetically apparent in the case of some advertisements directed toward children. The disparity of knowledge between the manufacturer and the consumer is too great.

When an individual is told that the maker of a dentifrice has had hundreds of scientists working and has spent millions of dollars to develop a miracle ingredient that will prevent tooth decay if dabbed on the toothbrush once a day, he believes it. He believes further that the Government doesn't allow advertisers to make claims that are false or half true.

He doesn't know that only a few individuals developed the miracle ingredient; that, often, its germ-killing qualities have never

been tested in the mouth and that, even on the laboratory plate, the magic drug killed only some of the bacteria. He doesn't realize that the dentists or the hygienist pictured in the ads is merely an actor or actress in a white coat. He misses the asterisk and the fine print which qualifies the broad claims made in the bold print. In short, the consumer is completely taken in. The unscrupulous among the advertisers know how to take him in, and they exploit him mercilessly and endlessly.

If this exploitation resulted only in economic loss to the consumer, perhaps it could be excused. But, as has been demonstrated, it does not stop there. The purchase of the product is lulled by the advertising into a false sense of security concerning his physical well-being; he is encouraged to neglect his health.

The American Dental Association has done as much as it is possible to do to counteract the effects of misleading dentifrice advertising. The association has distributed hundreds of thousands of copies of this leaflet, Don't be Misled ———, which I should like to submit. We have developed and disseminated sound information such as that contained in the leaflet entitled "Toothbrushing" and in the brochure, Diet and Dental Health, both of which I submit for the record.

In addition, the association, recognizing the need for sound and uniform scientific methods to replace the many and varied techniques employed in studying the possible therapeutic effects of dentifrices, sponsored in 1953 a conference to develop uniform standards and procedures in clinical studies of dental caries. This conference, which was attended by 50 of the foremost authorities in the field, resulted in the publication of the report, Clinical Testing of Dental Caries Preventives, which is offered for the record. This report is available to all who contemplate clinical studies of the effectiveness of dentifrices in controlling decay, and it was our hope that the sound principles set forth in its pages would be followed in testing new products.

Since its inception nearly 30 years ago, the council on dental therapeutics, an agency of the association, has evaluated dentifrice advertising claims and has issued reports periodically for the information of members of the profession.

It is evident, however, that all the efforts of the association hitherto have failed to prevent or neutralize the effects of the misleading advertising claims which the dentifrice manufacturers continue to issue. The problem of combating a multi-million-dollar sales campaign is one which the limited facilities of the association cannot solve.

We, therefore, have turned on several occasions to seek the assistance and intervention of the Government agency charged with the responsibility of controlling false and misleading advertising. In January 1956, the Federal Trade Commission was requested to take action regarding claims then appearing in dentifrice advertising. It was suggested that the FTC give consideration to calling a trade conference of dentifrice advertisers with a view to adopting an appropriate advertising code for the dentifrice industry. In reply, the Commission indicated, in effect, that it was powerless to act. It was pointed out that—

in Commission proceedings, the burden of establishing the falsity of claims is upon the Commission. The mere fact that advertisers have not adequately

established that the claims made for their products are true does not provide sufficient basis for the Commission to sustain action under its procedure to require their discontinuance.

The Commission stated, further, that an advertising code, to be effective, must be capable of enforcement by mandatory means.

A similar response was received by the California State Dental Association, the FTC stating that—

* * * the Commission bears the burden of proving that challenged representations are, in fact, false and misleading. It is not sufficient to establish that the advertiser does not possess sufficient evidence to clearly support the validity of his claims.

Copies of the above correspondence are offered for inclusion in the record.

(The matter referred to is as follows:)

AMERICAN DENTAL ASSOCIATION,
January 31, 1956.

MR. EDWARD F. HOWREY,
Chairman, Federal Trade Commission, Washington, D. C.

DEAR MR. HOWREY: The American Dental Association, with a total of more than 84,000 members, has noted with increasing concern the character of much of the advertising for dentifrices in all types of mediums. There is a growing conviction that many advertising claims for dentifrices are misleading and detrimental to the dental health of the public. This conviction has found expression in the resolution adopted by the house of delegates of the association in 1953, a copy of which is enclosed. Since 1953, the practices in dentifrice advertising have caused many members of the association to enlarge their concern.

A few examples of claims which are considered to be misleading are:

"The world's most effective weapon against tooth decay."
"Magical new fluoride toothpaste * * *"
"Saves your teeth from decay * * *"
"Just one brushing destroys decay- and odor-causing bacteria * * *"
"To give up to 7 times longer protection against tooth decay * * * With just 1 brushing * * *"
"Protect your child's teeth with the toothpaste that destroys decay bacteria best."

In the judgment of the council on dental therapeutics of this association, no presently available dentifrice has been adequately demonstrated to provide important protection against tooth decay under ordinary conditions of use. The procedures and policies of the council on dental therapeutics are clearly revealed in the publication, Accepted Dental Remedies, copy of which is enclosed. Quite recently, the association has published a brochure, Clinical Testing of Dental Caries Preventives, which contains the principles which should be observed in the performance of clinical tests of dentifrices. A copy of this is enclosed for your information.

It would appear to be particularly significant that, in the past 5 or 6 years, there has been a rapid shift in advertising emphasis from ammoniated to cholorophyllin to antibacterial to antienzyme and now to fluoride dentifrices, all with an assortment of misleading claims. This indicates the inability of the firms to achieve public confidence in any one type of dentifrice with asserted prophylactic value against dental caries.

The association believes that it would be in the best interest of the public and of the firms involved if common agreement could be reached on the validity of advertising claims for this type of product. It is requested, therefore, that the Federal Trade Commission give consideration to calling a trade conference with a view to the adoption of an appropriate advertising code for the dentifrice industry.

If the Commission considers this request favorably, you may be assured that the cooperation of the association and its scientific agencies is fully at your disposal.

Very truly yours,

HAROLD HILLENBRAND, D. D. S.,
Secretary.

JOINT RESOLUTION OF THE COUNCIL ON DENTAL THERAPEUTICS, THE COUNCIL ON DENTAL RESEARCH, AND THE COUNCIL ON DENTAL HEALTH

Whereas many dentifrices, mouthwashes, chewing gums, and other products are now being promoted to the public by advertising containing direct or implied claims that such products are effective in preventing dental caries and other dental diseases; and

Whereas many of these advertising claims are based on inadequate scientific evidence and are detrimental to public health, since they tend to discourage well-recognized and acceptable dental-health procedures, such as proper toothbrushing and avoiding excessive exposure to sugar-containing substances; and

Whereas much of the advertising for these products untruthfully suggests that members of the dental profession are participating in the advertising and promotion of these products of alleged health significance: Therefore be it

Resolved, That the American Dental Association call the attention of the public in the strongest possible terms to the serious danger to health which arises out of the present flood of inaccurate and untruthful claims in advertising for dentifrices and other dental products; and be it further

Resolved, That the manfacturers of these products and their advertising agencies be urged to cease those practices which tend to destroy the confidence of the public in the integrity of all advertising and in the reliability of all advertised products and services; and be it further

Resolved, That the members of the dental profession be urged in their daily practices to communicate to every patient scientific information on the present status of preventative measures for dental diseases and on the recommended procedures for maintaining the highest level of personal dental health.

Adopted by the house of delegates of the American Dental Association, September 1953, Cleveland, Ohio.

FEDERAL TRADE COMMISSION,
Washington, February 2, 1956.

AMERICAN DENTAL ASSOCIATION,
Chicago, Ill.
(Attention: Harold Hillenbrand, D. D. S., secretary.)

GENTLEMEN: This will acknowledge your letter of January 31, addressed to former Chairman Howrey, in which you allege that many advertising claims for dentifrices are misleading and suggest the calling of a trade conference for the dentifrice industry.

Your letter is being referred to the Commission's Bureau of Consultation, which is responsible for its trade-practice-conference program. You may be sure that your suggestion will receive serious consideration.

Sincerely yours,

ROBERT M. PARRISH, *Secretary.*

APRIL 23, 1956.

Mr. ROBERT M. PARRISH,
Secretary, Federal Trade Commission,
Washington, D. C.

DEAR MR. PARRISH: In your letter of February 2, you stated that the association's suggestion for the calling of a trade conference for the dentifrice industry was being referred to the Commission's Bureau of Consultation.

I am writing to inquire whether or not any action has been taken since no word has been received from the Bureau.

Faithfully yours,

HAROLD HILLENBRAND, D. D. S., *Secretary.*

MAY 17, 1956.

MR. ROBERT M. PARRISH,
Secretary, Federal Trade Commission,
Washington, D. C.

DEAR MR. PARISH: While I recognize that Federal agencies have heavy programs, common, courteous business practice recognizes the acknowledgment of letters of inquiry. I will appreciate your immediate response to my letter of April 23 which relates to my original inquiry of January 31, 1956.

Very truly yours,

HAROLD HILLENBRAND, D. D. S., *Secretary.*

FEDERAL TRADE COMMISSION,
Washington, D. C., May 18, 1956.

AMERICAN DENTAL ASSOCIATION,
Chicago, Ill.
(Attention Harold Hillenbrand, D. D. S.)

GENTLEMEN: This is in reply to your letter of yesterday, relating to your original inquiry of January 31, 1956, regarding dentrifrice advertising.

As indicated in my acknowledgment of your letter, dated February 2, a copy of which is enclosed, the matter was thereupon referred to the Commission's Bureau of Consultation. I am asking the Director of that Bureau to write you regarding its present status.

Sincerely yours,

ROBERT M. PARRISH, *Secretary.*

FEDERAL TRADE COMMISSION,
Washington, D. C., May 21, 1956.

Mr. HAROLD HILLENBRAND, D. D. S.,
Secretary, American Dental Association,
Chicago, Ill.

DEAR MR. HILLENBRAND: This will confirm the information conveyed in Mr. Parrish's letters to you of February 2 and May 18, 1956, to the effect that your January 31, 1956, letter requesting a trade conference for the purpose of adopting an appropriate advertising code for the dentifrice industry had been referred to this Bureau for its consideration.

Your association's letter application has been and is currently receiving the active study and consideration of this Bureau's Division of Trade Practice Conferences.

It is anticipated that the Bureau's report will be transmitted to the Commission in the near future. You will be promptly advised of the Commission's decision.

I regret the failure of this Bureau to acknowledge its receipt of your association's application by reference from our Secretary, and assure you that failure in that respect was entirely inadvertent.

Very truly yours,

CHARLES E. GRANDEY,
Director, Bureau of Consultation.

FEDERAL TRADE COMMISSION,
Washington, D. C., May 29, 1956.

AMERICAN DENTAL ASSOCIATION,
Chicago, Ill.
(Attention: Dr. Harold Hillenbrand, Secretary.)

GENTLEMEN: The Commission has given careful consideration to your letter of January 31, 1956, and enclosed copy of a resolution adopted September 1953, by the house of delegates of your association, both with reference to dentifrice advertising.

The course of action suggested in your January 31, 1956, letter relative to current dentifrice advertising, namely, the calling of a trade conference with a view to the adoption of an appropriate advertising code for the dentifrice industry, would be a voluntary procedure. An advertising code or advertising rules, to be effective, must clearly define the legal requirements pertaining to the particular advertising practices presently or potentially involved and be capable of enforcement by mandatory means.

In this connection, the Commission has noted your statement, relative to certain current dentifrice claims, that in the judgment of the Council on Dental Therapeutics no presently available dentifrice "has been adequately demonstrated to provide protection against tooth decay under ordinary conditions of use." In Commission proceedings, the burden of establishing the falsity of claims is upon the Commission. The mere fact therefore that advertisers have not adequately established that the claims made for their products are true does not provide sufficient basis for the Commission to sustain action under its procedure to require their discontinuance.

In view of the voluntary nature of the proceeding suggested in your letter and the difficulty of clearly delineating the line of demarcation between permissible advertising and advertising which is violative of the Commission Act, as well

as the apparent lack of clinical scientific evidence, the Commission has decided not to undertake the type of proceeding suggested in your January 31, 1956, letter.

The Commission is, however, most interested in matters affecting the health of consumers. It has been and will continue to be interested in the claims made by individual companies for their dentifrices, and wishes to express its appreciation to your association for its offer of cooperation and the use of its scientific agencies in connection with its treatment of advertising claims for dentifrices.

It is our feeling that your association, through its scientific agencies, could render valuable service to the public by undertaking clinical studies of dentifrices which it has reason to believe are being falsely advertised. In the event your association is willing to undertake research of that nature, the Commission will be glad to direct its Division of Scientific Opinions to consult with your representatives to the end that the results of the research will meet the requisite legal criteria.

By direction of the Commission.

ROBERT M. PARRISH, *Secretary.*

Dr. CREIG. The association believes that the advertising claims which have been presented here today are misleading within the meaning of section 15 of the Federal Trade Commission Act, which provides:

(a) (1) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.

The association believes that, by allowing the dentifrice advertisers to continue to make misleading claims without taking appropriate enforcement action, the Federal Trade Commission is failing to discharge its statutory responsibilities.

Where the health of the public is involved, as it is here, the Government is completely justified in requiring a high standard of responsibility from industry. At the present time, that standard is lacking. Dentifrice manufacturers have been and are selling health promises to the American public with no apparent concern as to whether such promises can be fulfilled; history demonstrates that, in the vast majority of cases, they have not approached fulfillment. A long list of successive advertising themes have been pushed strenuously and then abandoned when their selling power disappeared.

The burden of demonstrating the validity of therapeutic claims in advertising belongs morally, ethically, and logically with the party asserting them. The current concept that such claims must be considered to be true and unchallengeable until disproved by the public is fallacious and demonstrably ineffective.

Based on the 30 years of experience which the association's council on dental theraupeutics has had, it is our opinion that the FTC does not have the facilities to evaluate the claims for dentifrices, let alone the claims for the thousands of proprietary drugs which are being marketed today. It is hopeless and naive to expect the small scientific staff of the FTC to establish the truth or falsity of every claim which the advertisers, by whim or otherwise, feel like making. This is not to say that something could not be done about the blatant and obviously misleading claims that frequently appear.

Parenthetically, it might be observed that perhaps the Food and Drug Administration is more adequately staffed and equipped than the Federal Trade Commission and, thus, may be better able to control dentifrice and drug advertising. It would seem, moreover, that this function would dovetail efficiently with the Food and Drug Administration's existing jurisdiction over new drugs and labeling.

In the final analysis, however, it appears that the answer to the problem lies in the adoption of legal remedies and procedures which would shift the major burden of proof from the government to the advertiser. There would appear to be no sound reason why advertisers who choose to make representations as to the efficiency of their products in preventing or curing disease should not, upon reasonable cause shown, be called upon to substanitate such representations with scientifically acceptable evidence. This might be accomplished by establishing requirements similar to those now applied by the Food and Drug Administration in determining the safety of drugs before new drug applications may become effective.

There are, of course, other remedies that might be applied effectively to control the careless and reckless use of therapeutic claims in advertising. This, however, is a proper function for legal and legislative experts, rather than for health scientists.

We are here today only to point out that some regulatory mechanism is sorely needed. The existing system is not controlling abuses in dentrifice advertising. The ADA and the Academy of Periodontology and health organizations throughout the country agree that something more needs to be done.

The association, therefore, welcomes this opportunity to lay these facts before this committee. It is requested that your attention be given to the solution of the problem.

Thank you very much.

Mr. BLATNIK. And thank you, Dr. Creig.

Are there any questions?

Mr. MEADER. I'd just like to ask Dr. Creig one question.

Dr. Creig, has the American Dental Association or any other group or individuals in the dental profession presented to the Federal Trade Commission as much information as you presented to this committee here this morning with respect to misleading advertising of dentifrices?

Dr. CREIG. I will ask our Mr. Conway, our secretary, but I would say I don't believe so.

Mr. CONWAY. I will comment on it, first, and ask Dr. Pearlman to comment, because his agency is directly involved. But I am sure this much information, this type of development, has not been presented to the Federal Trade Commission. We have initiated overtures to them so we could bring to their attention this type of thing, but we have never gotten far with the first attempt to consult with them or to bring this type of information to their attention.

Mr. BLATNIK. Mr. Conway, what do you mean, you have not gotten very far in the attempt to submit this type of information? Did you ask for a hearing or a conference?

Mr. CONWAY. We asked the Federal Trade Commission if they would agree to call the dentifrice manufacturers and the association scientific people together to discuss the possibility of establishing a fair-trade-practice conference leading toward, perhaps, the adoption

of rules of fair practice for the dentifrice-manufacturing industry, and the Commission refused to consider that request.

Mr. MEADER. Well, Mr. Chairman, if I may pursue this, it strikes me, although I am not sure I am able to competently judge it, that a great deal of effort has been put into the preparation of material for this hearing for the committee, and, if you were asking the Federal Trade Commission to become active in this field, it seems to me you might well have presented this material and made a case before them. Then, if they didn't act, there would be a basis for saying they were neglecting their statutory responsibilities. But, if you have not presented to the Federal Trade Commission a prima facie case such as you have presented to this committee, I am not so sure you can charge them with dereliction.

Mr. CONWAY. Well, I will say this. When this committee graciously asked us to do this job, we recognized that the committee was interested in reviewing the material which we were going to develop. We had a full intention of doing the same thing for the Federal Trade Commission if they would give us any indication at all that they would call us in and call the manufacturers in and go over this problem on a relatively long-term basis, because it would probably have taken more than one conference. But we were fully prepared to do the same thing if we had been given any indication from the Commission that they would review and take into consideration——

Mr. MEADER. You felt you were given the "brushoff"?

Mr. CONWAY. That is exactly it.

Mr. PLAPINGER. Are you aware of any action the Federal Trade Commission has taken against excesses in dental advertising?

Mr. CONWAY. I know of none in the recent history anyway.

Dr. CREIG. Our correspondence led us to believe that.

Mr. HARDY. I think, Mr. Chairman, one question that would be involved in the aspect Mr. Meader raised is whether or not, in the view of the American Dental Association, the information which is presented to the committee would actually constitute the kind of information which the Federal Trade Commission said they would have to have. And I gather that this doesn't, in itself, prove that these claims are false, but, at least, it would prove they are misleading.

Mr. CONWAY. I am happy you brought that up, because I believe we felt that way. We felt they asked us to perform a virtually impossible task to comply with the requirements set out in their letter, that there would have to be a direct proof of falsity in these claims, which I don't think anybody is equipped to do. We were fully prepared to show the same type of information as we have here to show that the advertising claims, in our opinion, are both misleading and deceptive.

Mr. HARDY. You are not prepared to say that these claims are absolutely false, but that they are misleading and deceptive.

Mr. PLAPINGER. Which is all that is required under the FTC Act.

Mr. MEADER. I'd just like to ask one more question. Is it the official position of the American Dental Association that the statute under which the Federal Trade Commission operates should be so amended as to require evidence of false and misleading advertising by any industry or any company; that the burden of proof is upon the manufacturer making the claims, or the truth of the claims rather

than otherwise; that the Government must prove the falsity before they can proceed against it?

Mr. CONWAY. We don't think the act requires that the burden of proof be placed upon the public. We think that the rulemaking power of the Federal Trade Commission could well be changed, if it needs changing, to require that the industry, the manufacturers, the testers have the burden of proving the claims that relate to health. We have been informed that they do not do that today.

Mr. MEADER. Well, I think that is a major change in our policy with respect to Federal enforcement procedures, to make a man come in and prove his innocence rather than to presume he is innocent and make the one proceeding against him as doing something wrong have a case.

Mr. CONWAY. I don't think it is a question of innocence or guilt at all. I think it is a question of proving scientific validity of claims made that are supposed to have a scientific or health effect.

Mr. MEADER. What I am speaking about—you are talking about dentifrices.

Mr. CONWAY. That is right.

Mr. MEADER. But you would not make a different rule for dentifrices or a weight-reducing remedy or some of these things we have been looking into, or any misrepresentations in advertising that are false and misleading. If you were recommending that the burden of proof be upon the person selling his wares, or hawking his products, that everything he says is true or he cannot say it, you would have a terrific effect upon advertising in this country and, also, upon the marketing of products.

Dr. PEARLMAN. There is a definite and important distinction between products that are concerned with health and products that are not concerned with health. The association is not suggesting that it is important that a shirt manufacturer should prove that his shirt doesn't shrink more than 1 percent, or something like that. If you buy that shirt and it is misrepresented, you have lost the money you have put into the shirt——

Mr. MEADER. Before you go any further, there is no claim made in your statement today that there is anything dangerous in this——

Dr. PEARLMAN. There is, sir.

Mr. MEADER. But only to the extent it may deceive. It's dangerous because you say there is no need to brush your teeth any more because the protection will last 12 hours, but it is not like the new drug applications where it must be approved before they can be marketed. It is not that kind of health hazard involved here.

Dr. PEARLMAN. There is, from a standpoint of safety. And, of course, it is to be hoped that none of these products that are marketed—anything that is used on the body should be safe. And it is to be hoped that this kind of regulation is in effect. From the standpoint of safety, certainly, I think it is essential that anything that goes into the mouth must be shown to be nontoxic. But, from the other standpoint, the health standpoint which Dr. Lyons discussed extensively, the hazards that arise from neglect of treatment when treatment is needed—this, to us, sir, is just as serious as any false health claim can be.

Dr. LYONS. May I pick up at that point, because I think it is important to have Mr. Meader understand the answer we have in

mind. Suppose, as an example, Mr. Meader, your wife told you one morning that your breath was bad. And, if she were familiar with the acetone that she uses to take fingernail polish off her fingernails, she might suggest to you that your breath smells exactly like that acetone that she uses. And she or you might decide, "Well, I can buy a tube of that toothpaste up there that tells you that you can brush bad breath away." The acetone odor to your breath is an important symptom that dentists and physicians recognize as a symptom of uncontrolled diabetes where a marked degree of acidosis prevails. And suppose you use this dentifrice for 3 days or a week or a month, and then somebody picks you up off the street in a state of coma because of your uncontrolled diabetes which was not recognized because you were lulled into a sense of security on the matter of your breath. Would you claim then—suppose you had lost your life as a result of that coma——

Mr. MEADER. Then I would not make any claims. [Laughter.]

Dr. LYONS. But you would have been damaged by the claim that XYZ toothpaste brushes away the acetone odor of a breath related to uncontrolled and untreated diabetes.

Mr. MEADER. Well, obviously, we cannot conclude any discussion on this philosophical level, but I just wanted to know if it was the position of the American Dental Association that the whole philosophy of the enforcement of the provisions relating to misleading advertising be converted to one where the advertiser had a burden of proof or a scientific demonstration of the validity of his claim before he be permitted to make the claim, rather than the reverse, because there is a philosophy of Government involved in that. It is something that this committee could not decide anyhow because there would have to be a change in the legislation. But I just wanted to know because it seemed the American Dental Association was putting itself in the position of recommending that the burden of proof be upon the individual rather than upon the Government in any of these enforcement proceedings.

Dr. LYONS. May I comment further? The individual States have recognized their responsibility in the matters of health, and that is the reason they have set up boards of examiners for physicians and dentists and other provisions. This material goes to interstate commerce and that puts the responsibility of some sort on the Federal Government.

Furthermore, I would like to point out in connection with the Federal Trade Commission that about 20 years ago—I can't give you the exact date, but it was approximately 20 years ago—the council on dental therapeutics of the American Dental Association was interested in what the Federal Trade Commission might do in this connection; and it was suggested that I, as a member, bring the Commission's attention to a great many dentifrice advertisements and that the council might subsequently serve as an expert witness.

We have bumped into this sort of problem with the Federal Trade Commission. They were very frank to point out—I believe they stated an observation that is pretty generally recognized—that a certain advertising "gimmick" wears itself out in about 6 months or a year. It takes the Federal Trade Commission that long or longer to investigate a claim. And they pointed out that, by the time we get through with this hearing and are ready to suggest a cease-and-

desist order, that these firms will say, "Well, why, sure, we will sign a cease-and-desist order; we dropped that claim 6 months ago.

Mr. CONWAY. Might I suggest, Mr. Chairman, that perhaps it might be worthwhile that the committee address questions to the FTC witnesses who I understand are to appear tomorrow, whether or not under existing law with respect to health claims in advertising, whether or not they could require under existing law, perhaps with change of regulations, that the testers take the burden of proof on health claims in their advertising. It is our opinion that it could be done without a change in the law. (See appendix, exhibit 5, p. 171.)

Mr. BLATNIK. Thank you for the suggestion. We will certainly give it consideration.

Mr. PLAPINGER. Excuse me, Mr. Chairman, may I ask just one question?

There was a suggestion concerning the drafting of a proposed code of fair practice. Would the American Dental Association have any objection to presenting to the Federal Trade Commission such a proposed code?

Mr. CONWAY. We would be happy to join with them in preparing that code. Whatever help we could provide in drafting the code would certainly be available.

Mr. MEADER. Have you already prepared what you think should go into such a code?

Mr. CONWAY. No, I don't think we have gone that far, but we are prepared to help them do it.

Mr. BLATNIK. The hearing is adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12:28 p. m., the subcommittee adjourned, to reconvene at 10 a. m., the following day.)

FALSE AND MISLEADING ADVERTISING

(Dentifrices)

FRIDAY, JULY 18, 1958

HOUSE OF REPRESENTATIVES,
LEGAL AND MONETARY AFFAIRS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D. C.

The subcommittee met, pursuant to adjournment, at 10:30 a. m., in room 1501, New House Office Building, Hon. John A. Blatnik (chairman of the subcommittee) presiding.

Present: Representatives John A. Blatnik and Martha W. Griffiths.

Also present: Curtis E. Johnson, staff administrator; Jerome S. Plapinger, counsel, and Elizabeth D. Heater, clerk.

Mr. BLATNIK. The Legal and Monetary Affairs Subcommittee of the House Government Operations Committee will continue hearing on the Federal Trade Commission as it relates to dentifrice advertising claims, considering the testimony and the requests for investigation brought up by the American Dental Association yesterday. We will also have the followup query as to the status of the cigarette advertising and weight-reducing advertising which the committee heard last year and early this year.

We are privileged this morning to have with us the Honorable John W. Gwynne, Chairman of the Federal Trade Commission, and his staff associates and colleagues. And, Mr. Chairman, I welcome you this morning.

Mr. Chairman, yesterday we had the witnesses speaking in behalf of the American Dental Association. They presented a rather comprehensive and detailed statement expressing their deep concern on much advertising of dentifrices which tends to be misleading and in some cases false. Opening the testimony was Dr. Ralph Creig of Cleveland, Ohio, who is a member of the council on legislation. In his opening statment, he makes this statement, and I quote:

> The American Dental Association welcomes the interest of the subcommittee in dentifrice advertising. There has been a widespread conviction within the dental profession that many advertising claims for dentifrices are misleading and detrimental to the dental health and general health of the public.

In his concluding remarks, following presentation of samples illustrative of the type of advertising to which the American Dental Association was raising objection, which included eight of the prominent, perhaps leading, brands of dentifrices advertised and sold on the market, Dr. Creig said this:

> It seems obvious that only the Federal Government has the resources effectively to control misleading and deceptive claims for nationally advertised products.

It seems equally obvious that with respect to therapeutic claims for dentifrices, and it might be observed, for a variety of proprietary nostrums, such control is either woefully inadequate or nonexistent.

These are rather strong statements and we merely present them as statements representing the points of view of the representatives of the American Dental Association.

It is with interest that the committee wishes to pursue this further, Chairman Gwynne. So after your statement we will proceed with further questions and discussion to bring out more information on this whole problem.

STATEMENT OF JOHN W. GWYNNE, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. GWYNNE. Mr. Chairman, Mrs. Griffiths, I appear here this morning in response to the invitation of your chairman to discuss the operations of the Federal Trade Commission with respect to the advertising of dentifrices and also to discuss developments in cigarette advertising and weight-reduction advertising which have occurred since prior hearings on these subjects before this subcommittee.

I welcome this opportunity to discuss with you the problems of the Federal Trade Commission in policing the advertising of dentifrices, cigarettes, and weight reducers. Your committee hardly could have chosen products more illustrative of how costly and complex has become the task of adducing the scientific evidence needed to correct advertising abuses.

I also welcome the chance to say a few words later about the essential purposes of the Federal Trade Commission. I would like to emphasize, for example, that, to make the most effective use of our limited money and manpower, we must select our cases carefully in order to provide the public with the greatest protection in matters of health, safety, and economic morality. Such judgment must distinguish between vital threats and mere irritants, and must balance the degree of effort warranted to correct any particular evil against a lessening of effort in tackling other problems. We are not indifferent to deception in the sale of any product in commerce, but we have always believed it our duty to concentrate on those problems impressed with the greatest public interest.

But first let me discuss the operations of the Federal Trade Commission regarding the advertising of dentifrices, cigarettes, and weight reducers.

First, dentifrice advertising. The files, records and reports of the Federal Trade Commission indicate that the Commission has been for many years interested in and active in the dentifrice field. Some 34 orders to cease and desist have been issued by the Federal Trade Commission requiring various respondents to terminate unfair and deceptive practices of dental products. These orders are listed in an attachment entitled "Cease and Desist Orders Involving Dentifrices."

In addition, 27 stipulations have been negotiated in this area. Under the terms of these stipulations, the manufacturers of dental products have agreed to terminate various unfair and deceptive practices in the marketing of dental products. There matters are listed in attachment No. 2 entitled "Stipulations Dealing With Dental Products." I might say, Mr. Chairman, I have these exhibits and, with your permission, at the close of my statement I will be glad to offer them for either inclusion in the record or for such use as you wish to make of them, if that is agreeable.

(The matter referred to is as follows:)

CASES INVOLVING DENTIFRICES

Investigations by the Federal Trade Commission

Docket No.	Proposed respondent	Commodity	Date of order to cease and desist
606	The Mennen Co	Toothpaste	Mar. 3, 1922
1462	Pepsodent Co	do	Sept. 23, 1929
2009	Western Bottle Manufacturing Co	Dr. West's toothpaste	Dec. 12, 1932
2547	New England Collapsible Tube Co. and Robert P. Gust Co.	Dental creams and toothpaste (assorted brands).	Jan. 29, 1936
2502	Sterling Products Co	Dental preparations	Feb. 11, 1937
2507	Banner Novelty Co	Dental creams (assorted brands).	Oct. 1, 1935
2864	Mills Sales Co	Honor brand dental creams	Sept. 25, 1936
3064	Trade Laboratories, Inc	Society brand dental creams	Aug. 28, 1937
3070	Mills Sales Company of New York, Inc	Dr. Ross' toothpaste, Royal Blue dental cream.	July 10, 1937
3074	Kolynos Co	Kolynos toothpaste	June 5, 1937
3113	William A. Woodbury Sales Co., Inc	Dental creams	Dec. 8, 1938
3120	Gotham Sales Co., Inc	Dr. Ross' and Dr. Sach's dental creams.	Sept. 3, 1938
3142	Rex Merchandise Corporation of America	Dental creams (assorted)	May 16, 1941
3390	D. J. Mahler Co	Phyllis Maybelle dental creams.	June 28, 1938
3554	Universal Trading Co., Eastern Distributing Co., the National Products.	Toothpaste	Jan. 19, 1939
3584	New York Sales Co	Toothpaste and toothbrushes	Feb. 7, 1939
3587	The Kolynos Co	Kolynos toothpaste	June 20, 1939
3596	The R. L. Watkins Co	Dr. Lyons toothpowder	Sept. 28, 1942
3726	Hyral Distributing Co	Hyral	Apr. 3, 1941
3732	Marlborough Laboratories, Inc	D. D. S. toothpaste	Mar. 20, 1941
3791	McKesson & Robbins, Inc	Calox toothpaste	Dec. 28, 1939
3833	Super Franklin Co	Dentifrices	Oct. 10, 1941
3910	Mills Sales Company of New York et al	Toothpaste	Apr. 12, 1940
3969	Neo-Vim Co	Hi-Ho toothpaste	June 14, 1941
3998	Thomsen-King Co	Dentifrices	June 12, 1941
4420	Bengor Products Co	Dental creams (assorted)	June 20, 1951
4505	Kemico	Teeth Whitener, Formulas A and B.	Aug. 6, 1941
4861	Bristol-Myers Co	Ipana	Nov. 15, 1949
4937	Procter & Gamble Co	Teel	Dec. 4, 1950
5015	Gotham Premium Novelty Co	Toothpaste and toothpowder	Mar. 21, 1945
5031	Zonite Products Corp. et al	Forhan's toothpaste	Apr. 23, 1952
5037	Detroit Soda Products Co., Aarons, Sill & Caron, Inc.	Crystal brand baking soda (as a dentifrice).	June 26, 1944
5126	Colgate-Palmolive-Peet Co	Colgate dental cream, Colgate toothpowder.	Sept. 1, 1944
5625	Web Distributing Co	Pyrozide toothpaste	June 5, 1950
6024	Vick Chemical Co., Colgate-Palmolive-Peet Co., William R. Bassett.	Dentifrices	[1]

[1] Dismissed.

Stipulations

File No.	Proposed respondent	Commodity	Date	Number of stipulation
1-8010	Wallace J. Clark et al	Hyral	Apr. 12, 1935	0848
1-9328	Leon M. Nelson	Nelson's toothpaste	Apr. 29, 1936	01374
1-10419	Tartaroff Co	Tartaroff	Feb. 2, 1937	01642
1-10560	Chas. H. Phillips Chemical Co	Phillips Milk of Magnesia toothpaste.	Mar. 11, 1937	01709
1-10564	Bristol-Myers Co	Ipana toothpaste	do	01714
1-11285	The R. L. Watkins Co	Dr. Lyon's toothpaste	Aug. 9, 1937	01843
1-11602	Zonite Products Corp	Forhan's toothpaste	Dec. 13, 1937	01987
1-11716	Phillips & Benjamin Co., Inc	Sterakleen toothpaste	Jan. 10, 1938	02003
1-12126 [1]	Dr. Johann Strasska, Inc., Ltd	Strasska toothpaste	Mar. 7, 1938	02058
1-12011	Iodent Chemical Co	Iodent toothpaste	Mar. 25, 1938	02083
1-12217	F. James Herman	Pyreagos	Mar. 29, 1938	02092
1-11364	William R. Warner & Co., Inc	Vince	July 19, 1938	02190
1-12132	Bost Tooth Paste Corp	Bost	Nov. 29, 1939	02466
1-14754	McCollum Laboratories, Inc	Isodent, Isomar, Isolax, Isoveg, Kelp.	May 27, 1940	02575
1-16208	James J. Walker, Jr	Walker's famous toothpaste.	Apr. 8, 1941	02773
1-16190	Eleanor H. Mack	Revel	Apr. 9, 1941	02777
1-16274	E. R. Squibb & Sons et al	Squibb	Feb. 10, 1942	02949
1-19[illegible]32	Mark W. Allen et al	Kontrol	July 8, 1946	03317
1-18873 (D. 3142).	Crown Laboratories, Inc	D. D. S.; Dr. Sach's toothpaste.	May 5, 1936	1705
1843 [2]	Dr. Johann Strasska Laboratories, Inc., Ltd.	Strasska's	Oct. 12, 1936	1843
1-9888	Clyde Foster	Nubrite	Dec. 20, 1937	2110
1-11288	Continental Sales Corp	Tiger	June 20, 1938	2211
1-10611 [3]	Colgate-Palmolive-Peet Co	Colgate	June 26, 1940	2867
1-17415 [4]	Modern Products, Inc., of America	Santay	Mar. 12, 1945	4001
1-20238	Carey Laboratories Corp	Medisalt	Jan. 15, 1947	7568
D. 5126	Colgate-Palmolive-Peet Co	Colgate dental cream and toothpowder.	Aug. 16, 1944	[5] C 31
1-9804	Star Novelty Utilities et al	Darmay; Zubrant	Dec. 24, 1936	1904

[1] Supplemental to stipulation 1843, file 1-9917.
[2] See supplemental stipulation No. 02058.
[3] Amended Aug. 9, 1949.
[4] Amended, Mar. 19, 1948.
[5] Amended, Aug. 9, 1949.

Mr. BLATNIK. All right; that is agreeable.

Mr. GWYNNE. By a third important method, the Commission has attempted to work out with the dental industry and the American Dental Association an industrywide approach to dental advertising which would result in voluntary compliance by the industry with high advertising standards. These efforts are continuing, but to date we have failed to achieve acceptable standards. This has been due primarily to lack of scientific evidence establishing an appropriate basis for standards. I shall discuss these efforts in some detail later in this statement.

Before discussing the basic problem of adducing competent scientific evidence in dental product advertising I should like to point out that the bulk of present-day dental product advertising does have one clearly recognizable virtue; it tends to promote dental hygiene. Even though all claims for a specific product may not be 100 percent valid, if the advertising prompts one who has not previously brushed his teeth to begin brushing them, I expect that most dentists would agree that some good has been accomplished. This is not to say, however, that this observation should be taken to excuse any false claims, but in this field it is extremely difficult to detemine whether or not a specific claim is true.

To do so requires facilities, personnel, and money which, to this point, have not been made available to the Federal Trade Commis-

sion on a sufficient basis to police and analyze the literally thousands of claims made for the literally hundreds of products in this field. This subject I shall also discuss subsequently, but let me now describe the problems which we face in this area.

Efforts to prevent or reduce the incidence of dental caries have occupied the time of many research workers in dental science for many years. The etiology of dental cavities is highly complex, with the result that efforts to control the condition have taken many directions.

There is now fairly general agreement that one of the principal factors in the causation of dental caries is the fermentation of carbohydrates on the surfaces of the teeth with resultant production of acid which attacks the tooth enamel and ultimately leads to a carious lesion. Based on this concept of the initiation of caries there have been numerous procedures proposed for its prevention, including the neutralization of the acid on the tooth surfaces by means of antacids; the use of germicides or other means of altering the bacterial flora of the mouth so as to reduce the number of acid-forming organisms; alteration of the diet so as to minimize the quantities of fermentable carbohydrates eaten; cleansing of the mouth by means of brushing or otherwise immediately after each exposure to carbohydrate food; the use of so-called antienzymes to reduce the formation of acid by the bacteria on the tooth surface; and efforts to increase the resistance of the tooth enamel to attack by dietary or other means.

The principal effort to control caries by dietary means has been the fluoridation of drinking water and, at the same time, efforts to control the condition by the topical application of fluorides to the teeth in the dentist chair have been utilized. Most recently fluorides have been incorporated into certain dentifrices with a view to exerting a local effect upon the tooth enamel.

Most of these measures have obtained some degree of success in preventing dental caries under certain conditions, but as yet there is no measure which is completely successful in preventing tooth decay. Some of the measures which have demonstrated limited success in controlling dental caries have been adopted by the manufacturers and purveyors of dentifrices and used as a basis for advertising and labeling claims.

The position of the American Dental Association and its council on dental therapeutics can perhaps best be summarized by the following statement taken from a letter addressed under date of January 31, 1956, by the secretary of the association to the Commission:

> In the judgment of the council on dental therapeutics of this association, no presently available dentifrice has been adequately demonstrated to provide protection against tooth decay under ordinary conditions of use.

Similar expressions of skepticism and conservatism with respect to some of the newer developments in the dentifrice field have appeared from time to time on the editorial pages of the Journal of the American Dental Association. However, at the same time, this journal and other reputable dental journals have published the reports of scientific investigators which serve as the bases of many claims currently appearing in the dentifrice advertising.

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Among these have been:

(1) An article reporting reduction in dental caries of between 50 and 60 percent obtained by toothbrushing with a "neutral" dentifrice immediately after eating (Fosdick, Journal of the American Dental Association, vol. 40, p. 133, 1950);

(2) A report showing approximately 20 percent reduction in dental caries through the use of an ammoniated dentifrice (Kerr and Kesel, Journal of the American Dental Association, vol. 42, p. 180, 1951);

(3) A report showing a reduction in dental caries of approximately 25 percent through the use of ammoniated dentifrices (Cohen and Donzanti, Journal of the American Dental Association, vol. 49, 1954, p. 185);

(4) A report showing a reduction in dental caries of between 50 and 60 percent through the use of an ammoniated dentifrice. (Lefkowitz and Venti, Oral Surgery, Oral Medicine and Oral Pathology, vol. 4, p. 1576);

(5) A report showing a reduction in dental caries of approximately 43 percent through the use of an ammoniated dentifrice (Henzchel and Lieber, Oral Surgery, Oral Medicine and Oral Pathology, vol. 5, p. 155);

(6) A report showing a 60 percent reduction in dental caries through the use of a dentifrice containing the antienzyme, sodium-N-lauroyl sarcosinate (Fosdick, Northwestern University Bulletin, December 21, 1953);

(7) A report showing a substantial reduction of dental caries in children through the use of a stannous fluoride dentifrice. (Muhler et al., Journal of Dental Research, vol. 33, p. 606, 1954);

(8) A report showing a reduction in dental caries of approximately 50 percent through the use of stannous fluoride dentifrice. (Muhler et al., Journal of the American Dental Association, vol. 50, 1955, p. 163);

(9) A report showing a reduction in caries of approximately 35 percent through the use of a stannous fluoride dentifrice (Muhler et al., Journal of the American Dental Association, vol. 51, 1955, p. 556);

(10) A report showing a 40 percent reduction of caries incidence in 165 adults through the use of a stannous fluoride dentifrice (Muhler et al., Journal of Dental Research, vol. 35, p. 49, 1956, abstracted in Nutrition Reviews for July 1956);

(11) A report showing a substantial reduction in caries among the schoolchildren in Bloomington, Minn., through the use of stannous fluoride containing dentifrice (Jordan and Peterson, Journal of the American Dental Association, vol. 54, p. 589, 1957);

(12) A report showing approximately 50 percent reduction in dental caries through the use of a dentifrice containing sodium dehydroacetate and sodium oxalate (Sulser, Fosket, Fosdick, Journal of the American Dental Association, vol. 56, p. 368, 1958.

Report No. 1 above is that which caused the Commission to modify stipulation No. 2867 involving Colgate dental cream by the addition of the proviso as follows:

> That the foam produced by Colgate dental cream removes "all" decaying food deposits lodged between the teeth or in the mouth; or that the use of such product will prevent tooth decay or dental caries: *Provided*, That nothing herein contained shall be construed as an agreement by respondent not to represent that cleansing of the teeth promptly after each ingestion of food will tend to decrease the incipience of dental caries.

References Nos. 2 through 5 are those relied upon by the advertisers of various ammoniated dentifrices. Reference 6 relates to a widely advertised antienzyme-containing dentifrice. References 7 through 11 are relied upon to support the claims made for a popular fluoride-containing dentifrice. Reference 12 deals with another antienzyme-containing dentifrice.

The Journal of the American Dental Association has also carried some reports of scientific investigations tending to cast doubt on the usefulness of certain types of dentrifrices as caries-control agents. An example is the report of Hawes and Bibby with respect to ammoniated dentrifrice which appeared in the Journal of the American Dental Association, volume 46, page 280, 1953.

The Commission's scientists agree with the council on dental therapeutics that some of the claims with respect to caries control appearing in current dentifrice advertising are not proven, but as a regulatory agency we must point out that in the event such advertising claims are challenged in a formal Commission proceeding the staff can only hope to utilize in support of the complaint the general expert testimony of competent dental scientists who will state that the claims made for the dentifrices and their special ingredients "have not been adequately demonstrated." These witnesses will not be in position to state that the claims are false because there have been no controlled clinical studies which could serve as a basis for such statement; and on cross-examination they could be expected to admit that the claims are possible but in their judgment have not as yet been established.

On the other hand, the advertisers can be expected to produce equally competent scientists who have carried out the clinical studies using the various advertised dentifrices, or the unique ingredients in such dentifrices, which they interpret as demonstrating some value in reducing the incidence of dental caries. Then, in rebuttal, an effort could be made to minimize the persuasiveness of these clinical test reports from the standpoint of experiment design; duration of the studies; age of the subjects, and so forth, but it must be remembered that the authors of these reports are competent dental scientists attached to reputable educational institutions, who will undoubedly endeavor to justify the conclusions which they have drawn from their experimental work.

An adequate clinical experiment designed to test the efficacy of a dentifrice as a caries-preventive agency is very expensive and time consuming. It is necessary to use hundreds of subjects in order that the test may have statistical validity and these subjects must be repeatedly examined by competent dental personnel. In many instances, these examinations have included the taking of X-rays.

We have never attempted to obtain an actual estimate of the cost that would be involved in such a study because of our budgetary limitations for such purposes but we can easily envision the expenditure of $25,000 to $50,000 in the testing of 1 or 2 dentifrices. Attached hereto as exhibits are photostatic copies of the 13 journal articles referred to above.

These are the basic problems which the Commission faces in formal action against manufacturers of dental products. Solution of these problems is a matter of fundamental economics. If the Congress desires to buy for the public adequate protection in the dental product advertising field, it has it in its power to do so. The Commission stands ready to carry out the required testing program, but lacks resources to do so.

As I noted above, the Commission has also promoted and encouraged efforts by the industry to regulate its own advertising. As early as 1937, the Commission's Division of Trade Practice Conferences authorized an inquiry to ascertain the views of the industry regarding a trade-practice conference, but these efforts failed because it developed that a majority of the manufacturers of dentifrices were antagonistic to the idea.

Again, in 1946, the Commission ordered its staff to "give consideration to the feasibility of holding a trade-practice conference for the dentrifice industry." Subsequent to considerable development work by the Division, and upon its request, the Commission authorized a trade-practice conference on its own motion on May 10, 1948. Following thorough study and industry contact by the Division, the Commission, on March 21, 1951, rescinded its action authorizing a trade-practice conference for the dentifrice industry by reason of industry opposition and the diversity of expert scientific opinion.

Thereafter, on January 31, 1956, the American Dental Association requested that the Commission give consideration to "calling a trade conference with a view to adoption of an appropriate advertising code for the dentifrice industry." The Chairman, in his reply dated May 29, 1956, informed the association that such a code or rules to be effective, must of necessity clearly define the legal requirements pertaining to the particular advertising and be capable of enforcement by mandatory means, that the burden of establishing the falsity of such claims was upon the Commission, and the fact that advertisers have not adequately established that the claims made for their products are true does not provide sufficient basis for the Commission to sustain an action to require discontinuance. In closing, the Chairman advised as follows:

> It is our feeling that your association through its scientific agencies could render valuable service to the public by undertaking clinical studies of dentifrices which it has reason to believe are being falsely advertised. In the event your association is willing to undertake research of that nature, the Commission will be glad to direct its Division of Scientific Opinions to consult with your representatives to the end that the results of the research will meet the requisite legal criteria.

The Commission has had no further communication in this matter from the American Dental Association.

At the same time that the Commission denied the request of the ADA for a trade conference, May 1956, the Bureau of Consultation drafted Suggested Guides for the Advertising of Dentifrices.

The proposed guides were submitted to the Division of Scientific Opinions for comment. It pointed out that many of the guides' provisions could not be sustained in an adversary proceeding in the event they were violated. No further action has been taken on these guides.

Now, cigarette advertising. You have asked also that I brief you on Commission activity in the field of cigarette advertising. In addition to its regular investigational and case work in this area, the Commission has been proceeding along two special lines of inquiry which I believe will be of interest to this subcommittee.

We have completed a consumer survey conducted for the purpose of determining primarily what results smokers expect from smoking filter-tip cigarettes. In the course of the survey, the Commission's Bureau of Investigation interviewed smokers of filter-tip cigarettes in widely scattered areas of the country who smoke over 10 cigarettes a day.

Approximately 40 percent of the total interviewed said they changed to filter tips for health protection, specifying throat irritation and cancer—mainly lung cancer—as the principal reasons. As to the amount of protection, while a majority indicated only a moderate amount, approximately 28 percent said they expect a considerable amount.

On the question of whether the advertising of a cigarette as a filter tip without any health claims being made for the filter implied health protection, approximately 27 percent of the persons contacted said that it did. On the question of whether an advertising claim of "Better filter for better flavor" would indicate health protection, about 20 percent said that it would. Regarding the reasons for the choice of the particular filter-tip brand smoked, approximately two-thirds indicated better taste.

The survey further shows that most of the persons contacted smoke the filter tips to a butt length of 1 to 1¼ inches and that they formerly smoked the plain tips to a slightly shorter butt. As to the comparative number of cigarettes smoked a day, more than half said they smoked the same number while approximately 30 percent said they smoked more filter tips.

We believe that this survey will be of material assistance in the administration of the cigarette advertising guides and also that it can be used in evidence in the event that formal action is necessary.

You will recall that Commissioner Secrest testified before your committee in July 1957 on the subject of Federal Trade Commission action in regard to cigarette advertising. He called to your attention the fact that the Commission had proceeded in a substantial number of cases involving health claims for cigarettes. These included 7 formal complaint cases beginning in 1934, culminating in 4 final orders, with 1 complaint still being tried. The Commission also has accepted stipulations from cigarette manufacturers in 17 matters.

As Commissioner Secrest stated, the Commission on September 15, 1955, adopted cigarette advertising guides for the use of its staff in evaluating cigarette advertising. At the time of his testimony, through the use of the guides, the Commission's Bureau of Consultation had obtained the voluntary discontinuance of over 75 objectionable claims for industry products. In the past fiscal year this work has continued

and we have obtained the revision or deletion of 66 additional objectionable claims.

From the time when the guides were disseminated in September 1955, and until about September 1957, there was general observance by the cigarette industry of all of their provisions. Numerous conferences with members of the cigarette manufacturing industry led to the omission or correction of copy before publication and on other occasions change of copy after publication.

We have had to proceed with meticulous care. We know that the major cigarettemakers in the United States have been making strenuous efforts to establish proof through extensive research that their advertising claims are justified. These companies, as you will know, are both financially able and determined to defend themselves against any ill-founded or poorly supported challenge to their advertising. We are quite aware—and I am sure they are, too—that to set up prematurely any definitive testing standards might result in prolonged litigation during which comparative health claims could be made to the detriment of the public interest.

We have believed that it is far better at this stage to approach the problem on the basis of cigarette advertising guides to our own staff. Here the purpose is to set forth clearly the boundaries of illegality in advertised claims for cigarettes.

One of the guides, however, needs a sharper definition.

Guide 2 prohibits representations that any brand of cigarette or the smoke therefrom is low or contains less tar and nicotine than any other brand when it has not been established by competent scientific proof and that such difference or differences are significant.

About September 1957, the Lorillard Co., for its Kent cigarette, commenced to stress in its advertising that Kent had less tars and nicotine than any other cigarette. This started off what is known in the Madison Avenue advertising circles as the tar derby. Presently, we have 5 or 6 other manufacturers all claiming directly or by implication that their particular brand has less tar and nicotine than all others. For example, the American Tobacco Co., in an advertisement in the Washington Evening Star on June 2, 1958, stated:

Attention all smokers!
The score on filter cigarettes has changed!
Now Hit Parade has America's best filter!
Over 400,000 filter traps!
Up to 43 percent higher filtration.

About the same time, in national newspaper advertising, the Philip Morris Co. claimed for its cigarette:

Now Hi Fi Parliament with recessed filter is best! No other popular cigarette delivers less nicotine and tar in the smoke, thanks to over 30,000 filter traps.

Liggett & Myers advertised:

Puff by puff today's L. & M. gives you less tars and more taste.

Likewise, Brown & Williamson Tobacco Co. has claimed:

Viceroy gives you more of what you change to a filter for.

I'm sorry, Mr. Chairman, I can't sing that. [Laughter.]
The United States Tobacco Co. stated:

There can only be one "best"! Look at the facts: With King Sano you get 61 percent less nicotine than with any other cigarette made. Less tars, too.

Now, we have here ads to which we referred, Mr. Chairman. I have no doubt that you and every member of the committee have read them. However, I will turn them over to you.

Mr. BLATNIK. At this point, Mr. Gwynne, these ads and others yet, 5 or 6 cigarette manufacturers claim to have less tars or nicotine than any other brands. Now, which of these are lying?

Mr. GWYNNE. Obviously, the thing is confusing and the American public is being deceived. Now, let's be frank about it, and we next take up how we think the truth can be gotten to the people, if I may be permitted. The question you raised is the very question we are very much interested in.

Now, since the fall of 1957, the Bureau of Consultation has asked each and every advertiser to submit "competent scientific proof" to justify its claims. Each one of them has supplied us with copies of tests made by themselves and by independent testing laboratories which purport to substantiate the claims made by each particular manufacturer.

Although these conflicting claims and conflicting test reports present an anomalous situation from the competitive standpoint, they have their brighter side from another standpoint. Regardless of which brand of cigarettes actually furnishes the least tar or nicotine to the smoker, the reports show that the manufacturers of several brands of filter-tip cigarettes are making a real effort to lower the content of these substances in the smoke of their cigarettes. This means that the manufacturers of some brands of filter-tip cigarettes are attempting to accomplish the purpose for which these cigarettes were originally popularized; that is, a reduction of the smoker's exposure to the noxious substances in cigarette smoke.

Mr. BLATNIK. At this point, Mr. Gwynne, may I ask, is it not true that this attempt to reduce the smoker's exposure to these noxious substances in cigarette smoke have actually only been made in the last year. Whereas, the filter tips have been ballyhooed for the past 5 years?

Mr. GWYNNE. That is right. I would like to be sure about that. I would like to ask Dr. Irish. It is my understanding your statement is correct. Isn't it, Dr. Irish?

Dr. IRISH. Yes. When the filter tip cigarette first began to be popular some 4 or 5 years ago, there were 1 or 2 brands that were probably making a sincere effort to produce an effective filter. Then we went through a period when the filter-tip cigarettes were not much different from nonfilter cigarettes. And within the last year then, we have seen a reversal of the pendulum and several of the manufacturers apparently are making an earnest effort to put out a product with reduced tar-nicotine content in the smoke.

Mr. BLATNIK. So after 5 years of drumming it into the heads of the American people that the filter does something for you, we find out it is only during the last year that the real efforts have been made on the part of some of these filter-tip cigarette manufacturers to reduce the tar and nicotine content.

Dr. IRISH. That is true in the case of some brands.

Mr. BLATNIK. You say the majority of the brands could not be.

Dr. IRISH. I am not so sure. It probably would be a majority.

Mr. BLATNIK. You had a conference early this year, I understand, Judge Gwynne, with the representatives of most if not all the filter-

tip cigarette manufacturers, seeking or hoping to reach an agreement on a method of standardizing testing procedures, to make it uniform.

Mr. GWYNNE. That is correct, Mr. Chairman. I take it up next in my statement. It may answer some of your questions. If not I will be glad to ——

Mr. BLATNIK Do proceed with the statement.

Mr. GWYNNE. In evaluating and examining the conflicting test reports in an effort to resolve the maze of competitive claims, it was learned that the various testing activities used methods which varied widely in certain essentials. We have found that some manufacturers do not obtain samples of their own cigarettes from the market place, but take them from production lines. Samples that have been tested of other firms' brands have been obtained in anywhere from the retail store nearest the testing laboratory to as many as 16 cities, with as many cigarettes being involved in the tests.

Another apparent great difference to be expected in test results is the amount of cigarette to be smoked. Some testing activities smoke a constant amount of cigarette, such as 47 millimeters. It should be borne in mind that cigarettes vary in lengths of 70 millimeters, 80 millimeters and 85 millimeters. It can readily be understood that smoking cigarettes of three different lengths will give a different result in tar and nicotine content.

Other laboratories test cigarettes to a constant butt lengh which varies all the way from a minimum of about 20 millimeters up to 37 millimeters.

Still another manufacturer tests his and competing cigarettes by taking a certain number of puffs from the cigarettes, ending up with butts of various lengths. The reason for this is that cigarettes vary as to weight and content of tobacco.

There was a great lack of uniformity among testing activities in the "tar determination." Of all the various sampling and testing methods used by those concerned, not one could be regarded as a "standard" test.

I would like to point out at this time that no Government agency, including the Food and Drug Administration, is making tests of the content of the smoke of cigarettes and, furthermore, no Government agency at this time has the necessary equipment, such as a smoking machine.

Because of the lack of a standard testing method in the industry, the Commission's Bureau of Consultation was authorized by the Commission on February 13, 1958, to hold a public conference for the purpose of providing the Commission with facts necessary to enable it to adopt testing specifications essential to a proper appraisal of test data on which advertising claims are based. In other words, what we are looking for is a yardstick that measures 36 inches for everybody, and not 35 for some and 37 for others.

In this connection, in February 1958, producers of cigarettes, testing laboratories, representatives of other Government agencies, consumer group representatives and magazine publishers, medical groups such as the American Medical Association and the National Cancer Institute, and others who could contribute, were invited to attend this public hearing. The hearing was conducted on February 26 and 27, 1958, by Mr. Charles E. Grandey, Director of the Bureau of Consultation. A public record was made of the hearing, and we under-

stand that over 100 copies of this record have been purchased from the reporting service by interested firms and individuals.

This meeting again made amply clear that there is a great divergence of opinion as to test methods in the tobacco industry to such an extent that even terminology is in dispute as to precise meaning, the word "tar" being an example.

Subsequent to the February hearing, the Commission's Bureau of Consultation has been in contact with a number of manufacturers and testing laboratories in a further effort toward the ultimate adoption of a standard method of testing.

As a result of this work, the Bureau of Consultation drafted a tentative standard or method to be followed in conducting tests of the content of smoke of cigarettes for the proposed purpose of evaluating advertising claims by the Commission's staff under its cigarette advertising guides. We secured a quantity of unbranded cigarettes, which were made up for us, of a uniform blend, representative of cigarette tobacco found in commercially sold cigarettes. We asked 4 cigarette manufacturers and 4 independent testing laboratories, including the American Medical association, to test samples of these unbranded cigarettes in accordance with the tentative method. The test method and the cigarettes were sent out during the last week of June 1958. We have not as yet received from those participating in this test all of their results, so at this particular time we cannot state if the tentative method will meet our needs.

The purpose of these tests is to determine if the tentative method is reproducible from laboratory to laboratory and if all laboratories can work with it with existing facilities.

We should like to point out that this effort on the part of the Bureau of Consultation is without precedent to our knowledge by any governmental agency or health group. We have high hopes that our efforts to devise a uniform testing method will be rewarded.

Now, weight-reduction advertising: On August 9, 1957, pursuant to the statement made by the Commission's representative before this subcommittee on August 8, 1957, there was submitted a list of 245 investigations conducted by the Commission regarding products advertised for use in reducing weight and showing the disposition of such cases.

At that time 23 investigations were reported as pending. In this group 2 formal complaints have issued, 8 of the investigations have been closed because of discontinuance of the practices or for other reasons, and 13 of the matters are now pending.

As of July 1, 1958, 31 additional investigations had been undertaken. In this group three formal complaints have issued. One stipulation to cease and desist has been accepted, 7 investigations have been closed because of discontinuance of the practices or other reasons, and 20 of the matters are pending. Lists showing the current status of each of these matters will be supplied to the subcommittee if you desire.

During fiscal year 1958 the Commission had issued 5 complaints challenging the advertising claims of weight-reducing drug preparations and has issued 2 orders to cease and desist from dissemination of certain claims for such products. The cases referred to are as follows:

1. General Products Corp.: This corporate respondent and two of its officers as individuals were charged in a complaint issued March 28,

1958, with having falsely represented that Pounds-Off would cause users to have a specific weight loss in a prescribed period of time, and that the "antihunger" ingredient in it was a new discovery.

2. Alleghany Pharmacal Corp.: This corporate respondent and two of its officers individually were charged in a complaint which the Commission directed issue June 24, 1958, with having falsely represented that "Hungrex with P. P. A." was safe to use by all persons, caused specific weight loss in a prescribed period of time, and would cause consumers to lose weight without dieting.

3. Practical Research Co.: A complaint identical as to charges in the Alleghany complaint was also, on June 26, 1958, directed to be issued against this company and its individual owner, regarding the product K–12.

4. Anderson Pharmacal Corp.: Identically as in the Alleghany and Practical Research matters, supra, the same charges of false or misleading advertising were contained in a complaint the Commission, on June 24, 1958, directed be issued against this corporate respondent and two of its officers individually, regarding the product Du–Dol.

5. Drug Research Corp.: Claims for the product Regimen–Tablets were challenged identically as in the Alleghany, Practical Research, and Anderson matters, supra, in a complaint the Commission, on June 24, 1958, directed be issued against the corporation, 2 of its officers individually, and 1 of the stockholders. This complaint contained an additional charge of falsity in advertising through use of representations that significant loss of weight resulting from increased excretion of body fluids would be of more than temporary duration. The company's advertising agency was also joined as a respondent.

6. Rennel Products.

7. Rennel Sales: In two orders issued simultaneously December 18, 1957, the Commission prohibited the four individuals, who operated these enterprises as copartners, from continuing to represent that Rennel Concentrate was a competent and effective treatment for obesity and would greatly reduce weight. The product was merely a laxative.

And, now, in conclusion, Mr. Chairman, I have presented a discussion of the Commission's record in three areas of false and misleading advertising involved in your inquiry. These are important areas. But, important though they may be, they are but a small segment of the whole area of false and misleading advertising and unfair practices, covered by the laws, for whose enforcement the Commission has responsibility.

The broader area contains countless froms of greed and trickery whose victims might be expected to suffer even greater hardship than the ladies who cannot lose weight without dieting. Consider, for example, the advertising of the miracle remedies for arthritis and asthma, or those "cures" for miscellaneous miseries that might be cancer. Consider, too, the slick schemes designed to get money away from elderly people scrimping along on meager retirement funds—the earn-money-at-home schemes that require precious investment with no likelihood of profit. And young people who may be misled by the gleaming white promises of dentifrices would be misled even more by worthless correspondence schools or spuriously advertised business opportunities. Also of grave concern are the "amazing" opportunities to buy fictitiously priced merchandise from

stores whose bait advertising has tricked customers away from reputable merchants.

The number of these schemes is legion; the variety of their methods is limited only by the ingenuity and cynicism of their promoters. But even this broad field I have been describing is only a small part of the area covered by the laws which Congress has passed to promote fair competition, maintain opportunity, and to preserve our system of free enterprise. For example, there is the matter of preventing undue concentration. Since the adoption of the 1950 Celler-Kefauver amendments to section 7 of the Clayton Act, the Commission has filed 26 complaints, challenging certain mergers and acquisitions. There are many other suits charging illegal discriminations, illegal promotion allowances, boycotts, restraints of trade, and price fixing. Many of these complaints are in the area where the greatest number of consumers may be injured; to wit, the production and distribution of food.

In determining the direction of Commission action or the amount in any area, certain limitations must be considered. I have already discussed the limitations due to presently unresolved scientific questions in certain fields.

Another limitation has to do with the manpower available to the Commission for any particular purpose.

Since the Commission was created in 1914, there have been not only additional duties placed upon it, but also there has been tremendous growth in the total number of businesses over which we have jurisdiction. It was estimated that in 1914 2 million businesses were subject to the jurisdiction of the Commission, whereas in 1958, there are approximately 4 million.

In 1914, the national gross volume of business was less than $40 billion. By 1957, this volume had increased more than tenfold to $433.9 billion. The total volume of advertising in 1914 was $1,302 million. Printer's Ink magazine suggested the total amount spent for advertising in 1957 was approximately $10,200 million. In 1918, the Commission had 689 personnel. In 1958, we have 750, 61 more than we had 40 years ago, while the number of statutes and the total amount of business under the jurisdiction of the Federal Trade Commission and the total amount of advertising have grown enormously.

Our annual budget is now about $6 million. The Commission must exercise a sound discretion in determining how that money must be spent to achieve the maximum result in all the many fields which Congress has established for it. We are often urged by outstide persons or groups to place more emphasis in certain fields. There are also others who urge that our activities in certain areas be curtailed or even eliminated. While we are glad to give serious consideration to these contending arguments, nevertheless, the final responsibility is upon the Commission. There, the law has placed it.

We must remember, too, the fundamental purpose for which the Federal Trade Commission was created. This was well expressed by its great promoter, President Woodrow Wilson, in the following language:

> **And the businessmen of the country desire something more than that the menace of legal process in these matters be made explicit and intelligible. They desire the advice, the definite guidance, and information which can be supplied by an administrative body, an interstate trade commission.**

Through the trade-practice conference and through advertising guides, we are trying wherever possible to offer the guidance to industry which the founders of the Federal Trade Commission had in mind. Thus, it is made easier for the well-intentioned to comply with the complex provisions of the law, and for the real violators to be singled out and brought into line.

This does not mean that fewer complaints will be filed. Our recent records show the contrary to be true. For example, in the fiscal year 1958, the Federal Trade Commission issued approximately 275 deceptive practices complaints. This figure represents 90 more than were issued in fiscal 1957 and 125 more than in fiscal 1956. Over the same period, the Commission issued approximately 235 deceptive practices orders to cease and desist which represents about 85 more than in fiscal 1957 and over 100 more than in fiscal 1956. In addition, 140 stipulations were issued and 1,706 matters were administratively handled, including assurances of discontinuance which resulted in the challenged practices being stopped without the necessity of formal action.

Mr. Chairman, that ends the statement I have prepared.

Mr. BLATNIK. Judge Gwynne, thank you for a very comprehensive statement covering several large areas.

If we may return back by subject order to the dentifrices, then we will proceed and follow the order of the subject matter of your preparted statement, Mr. Chairman.

Mr. Plapinger, will you start with your questioning?

Mr. PLAPINGER. Judge, on page 2 of your statement you refer to some 34 orders to cease and desist in the dental field, in an attachment. I wonder if Mr. Babcock could pass the attachment over.

Mr. BABCOCK. The cases and the stipulations are both on that attachment (handing to Mr. Plapinger). (See pp. 75, 76.)

Mr. PLAPINGER. I was interested in seeing the date of the last cease-and-desist order [examining the document], which is 1952, and in the case of stipulations, 1947. What action has been taken since then in this field by stipulation of discontinuance or cease-and-desist order?

Mr. GWYNNE. Why don't you ask Mr. Babcock. I don't have a copy of that form.

Can you answer that?

Mr. BABCOCK. What action has been taken since?

Mr. PLAPINGER. Yes.

Mr. BABCOCK. As far as I know this minute, these are the orders and stipulations. We do, of course, have a substantial number of investigations underway.

Mr. PLAPINGER. The Colgate case which is referred to on page 8, Mr. Babcock, what is the date of that? That is, the date of stipulation. Is that docket No. 5126?

Mr. BABCOCK. It is; yes.

Mr. PLAPINGER. Dated September 1, 1944?

Mr. BABCOCK. That's right.

Mr. PLAPINGER. In the statement on page 3, there is a reference to the voluntary compliance method and a statement that "these efforts are continuing, but to date we have failed to achieve acceptable standards." Now, I also call your attention to the fact that on page 13 of the statement, Judge Gwynne, the last sentence says that, "No further action has been taken on these guides."

Mr. GWYNNE. Of course, the guides were prepared; but when they were presented to the people on whom we rely for our scientific information, we were told that the scientific situation is now at such a state that you cannot prove those are false.

Mr. PLAPINGER. I understand that, sir, but the statement on page 3 is that the efforts are continuing the statement on page 13 that there has been no further action. I was interested in learning what form those efforts are now taking.

Mr. GWYNNE. Mr. Jamarik, who is in charge of that part of our work, will be glad to fill in there.

Mr. JAMARIK. The only concrete answer I can give to that question is that we are continually, both through our Division of Scientific Opinions as well as our liaison in contact with experts in this field, continuously exploring the possibility of new evidence, new scientific data, and so forth. But basically the problem as set forth is stated in the Chairman's presentation here this morning.

Mr. PLAPINGER. The American Dental Association yesterday, in response to subcommittee request, said that it would be glad to cooperate with the Commission in the formulation of advertising guides at the present time. The Colgate-Palmolive Co. issued a statement yesterday following our hearings and said that it "enthusiastically endorses any efforts by governmental agencies to assure the safety of the American consumer." In view of the willingness of both the leading dental professional organization in the country and the leading dental manufacturing company of America, what would be the position of the Commission with respect to calling the organizations in and the other manufacturers in at this time?

Mr. GWYNNE. Excuse me, I was going to answer. You can add to it if you wish.

I wish to say on behalf of the entire Commission and staff that we will be very pleased to cooperate with any group—manufacturers, dental association, dental colleges—anybody who can assist us in one problem that confronts us, and that we cannot by ourselves solve; and that is, the answer to these scientific questions. We are pleased to have the report you made. That is the first I had heard about that.

Mr. BLATNIK. Judge, I don't mean to interrupt. We talk about the problem—you present it as a difficult problem of presenting scientific evidence to either prove or disprove these claims made on very simple substances such as a dentifrice or weight reducer or a filter. It does not seem to be much of a problem to establish beyond any doubt the scientific validity of very complex drugs in the field of cortisone with arthritis and in the field of your mental drugs and your synthetic vitamins. There is no problem there at all. Why should it be a problem to establish scientific proof on these simple, more or less superficial items?

Mr. GWYNNE. Some of these items have been worked over and problems have been solved.

Mr. BLATNIK. Because no so-called wonder drug is released until whatever firm is making it, or whatever medical clinic agency approves, has complete substantiating data, laboratory data, results that can be duplicated by any other group or agency——

Mr. GWYNNE. I would like to be corrected, if I am not right, but that is true as to the safety. However, if after a drug is on the market and claims are made that the labeling makes claims for its efficacy

that it does not have, Food and Drug has to seize it and try that fact out and prove it, just exactly like we do.

Is that correct, Dr. Irish?

Dr. IRISH. That is definitely correct.

Mr. GWYNNE. Now, it is true those drugs you mention have stood the test of time.

Mr. BLATNIK. The burden of proof is on those who manufacture and promote their use; and the minute there is a hitch, we are able to check them.

Mr. GWYNNE. The burden of proof as to the safety. Yes; they must say that the drug is not unsafe. I am no great authority on that Food and Drug business; but if their claim is made of the lack of efficacy that its label indicates, that must be proven.

Mr. BLATNIK. I do not understand these two standards on these simple things.

Mr. GWYNNE. Could I refer to Dr. Irish, who is sort of an expert on that field?

Dr. Irish, do you want to elaborate a little there on what I have been saying?

Mr. IRISH. Well, you are approaching the question of the burden of proof before a product can be marketed or before claims can be made for it. Now, it is true, when a new article is introduced, its safety must be established, with the burden being on the sponsor of the article. There will be perhaps some consideration of efficacy as that bears on safety. But once the product has been marketed, then the claims that were made for it must be proceeded against by the other agency, just as in the case of the Federal Trade Commission, with the agency attacking the claim bearing the burden of proving it to be false.

Mr. PIAPINGER. But in your cigarette guides, for instance where there is a reference to the fact that there are conflicting standards in cigarette testing, for instance, your guide No. 2 says that this is one of the prohibitions, if it——

represents that any brand of cigarette, or the smoke therefrom, is low in nicotine or tars or contains less nicotine, tars, acids, resins, or other substances by virture of its ingredients, method of manufacture, make, added filter or for any other reason, or without any assigned reason, than any other brand or brands of cigarettes, when it has not been established by competent scientific proof applicable at the time of dissemination that the claim is true; and, if true, that such difference or differences are significant.

Now, if you establish such a standard for your own guides—which I presume have met with some industry acceptance—why could not the same kinds of guides be established with respect to dentifrices?

Mr. GWYNNE. Well, that guide does not shift the burden of proof which the law puts on us. We have to prove that. That guide is simply a restatement of the law.

Mr. KINTNER. Voluntary.

Mr. GWYNNE. It is voluntary—well, no, it is just direction to the staff. The cigarette people never accepted that.

Mr. PLAPINGER. Well, there has been some acceptance by the industry, I gather from your statement, with respect to the number of stipulations or discontinuance of objectionable advertisements.

Mr. GWYNNE. That is true, purely voluntary.

Mr. PLAPINGER. That is right.

Mr. GWYNNE. But nevertheless no cigarette company is obliged to accept any guide that we give out.

Mr. PLAPINGER. I understand that, sir, but the fact of the matter is that if the claim is not scientifically true, then it cannot be made according to your instructions given to your staff?

Mr. GWYNNE. It should not be made, that is right. And our instructions to the staff are that when you find one is made and they will not voluntarily give it up, then if you have the scientific proof to prove it, file the case.

Mr. BLATNIK. Not to interrupt, not on a specific thing but scientific proof, now here is an ad on dentifrices that certainly is not understating their claims I would say. Big lettters say, "Saves your teeth from decay." That is a pretty flat statement. To the left here it says, "Test after test by dentists proved it."

Now, here is what the representatives of the American Dental Association reported yesterday on this particular ad which advertises Super Amm-i-dent:

> To this day we have not seen a single report of a clinical study of Super Amm-i-dent with fluoride, either good, bad or indifferent. As far as we know, the clinical program mentioned in the firm's letter 3 years ago has still not been completed. We don't know where or how it is being conducted. Yet in October 1955, this ad proclaimed that—as it does here—"Test after test by dentists proved it."

The association says:

> We know of not one single dentist that has even tried to prove that Super Amm-i-dent with fluoride "saves your teeth from decay."

That is not only a misleading statement, that is a flat lie if I may be bold as to say.

Mr. GWYNNE. I am not familiar with that particular ad. I do not know if that has been called to our attention or not. However, let me say this, that if any of these ads that you have or the Dental Association had that they think violate the law and that the scientific knowledge is such that they can state that "We can prove it false," we certainly would be glad to consider filing complaint.

Dr. IRISH. May I add that this product contains fluoride; it is an ammoniated dentifrice and it is said to contain an antienzyme.

Now it is true that particular combination—I am willing to accept the statement by the gentleman yesterday—has not been clinically tested; but there is dental literature on each of those ingredients and we would have to face that if we were to assume the burden of saying that the claims for caries prevention in this ad are unwarranted.

Mr. BLATNIK. You mean you could not prove that these claims are unwarranted? But it is obvious if no tests have been made by the dentists that the company making Super Amm-i-dent cannot prove any tests.

I would just ask, where are your tests made? "Test after test made by dentists proved it." Say "where are your tests?"

Mr. PLAPINGER. In other words, you can measure the results of the test against the claims made in the advertising. I think that was the point in most of the American Dental Association's testimony yesterday.

Mr. GWYNNE. Here is the answer to that, it seems to me, and it is a simple question, the burden of proof. Now, they make claims and

the Dental Association says, "We do not know that they have any proof to establish the truth of their claims." That is an interesting observation, but legally it would not amount to 5 cents, not even that much.

What we have got to know is, who will come in and testify as a scientist, as an expert? Who will say, "I know the answer to this and that is false." That is what we do not have.

(See appendix, exhibit 5, p. 171.)

Mr. PLAPINGER. Judge, I am not minimizing the legal problems involved, but you certainly have the right of subpena duces tecum to call for their tests and measure the results of the tests against their advertising.

Mr. BABCOCK. Mr. Counsel, may I ask how, short of clinical testing?

Mr. PLAPINGER. Pardon?

Mr. BABCOCK. May I ask how can we do that, short of clinical testing?

Mr. PLAPINGER. If the test shows one thing and the advertising another. In other words, you just set the test and the advertised claim against one another. That is one instance in which possibly clinical testing would not be necessary, and I am not minimizing the necessity for clinical testing in other instances.

Mr. BABCOCK. But they match them. Here is the claim and here is what they submit as scientifically supporting that claim.

Mr. PLAPINGER. I think, Mr. Babcock, if you read the testimony that was submitted yesterday—and we will make a complete copy available with the advertised claims—that the principal burden of of the American Dental Association's remarks were concerned with the disparity between the advertised claims and the tests.

Mr. BABCOCK. Mr. Counsel, may I go back to that question you asked a minute ago as to what we were doing now.

I have refreshed information on that point. We have taken off with our radio and kinescope all dental advertising from radio and television and we are collecting elsewhere. Many of these are with our overloaded scientific bureau down there. We have not been insensitive to what is going on at the present time. As to however efficacious we are going to be in the immediate future, I cannot say. We by no means have turned our back on it.

Mr. PLAPINGER. Of course, also you might be missing a good bet, in the past at least, having to some extent turned you back on the American Dental Association.

Mr. BABCOCK. Well, we made our statements on that.

Mr. GWYNNE. I do not think we have. The last letter I sent them I never got an answer to.

Mrs. GRIFFITHS. Mr. Chairman, may I ask a question?

Mr. BLATNIK. Mrs. Griffiths.

Mrs. GRIFFITHS. Do you really have the authority to ask one of those advertisers to produce the tests before you start a suit?

Could you ask them, for instance on this dental advertisement where they say, "Many tests have been made," to come into your office and produce the tests?

Mr. BABCOCK. Yes; we do it every day.

Mrs. GRIFFITHS. You can.

Mr. BABCOCK. And, of course, they would gladly come forward with it because it is their case. They are glad to have us have them.

Mrs. GRIFFITHS. Then I fail to understand why——

Mr. BABCOCK. Then we are really on the spot we have pointed up here today. We have to counter it with scientific testimony if it is not true.

Mr. Irish and his staff can examine it, yes, and say it looks somewhat questionable from a scientific standpoint; but the courts tell us, and our own examiners tell us, come forward with your own clinical test. Refute this with similar or like testimony.

Mrs. GRIFFITHS. But in these cases where there never have been any tests, is the reason you have not asked them to appear simply because you do not have the time? You just have not gotten around to that person? Or do you believe other than the Dental Association has pointed out?

Mr. BABCOCK. We send out—I do not suppose there is a manufacturer who has not been questioned on every claim he has ever made by letter and by invitation.

Mrs. GRIFFITHS. Are you saying that these people on that ad did produce the test? Or have you not tested it yet?

What is the name of it?

Mr. BLATNIK. That is the Super Amm-i-dent.

Mrs. GRIFFITHS. Super Amm-i-dent.

Have they produced the test?

Mr. BABCOCK. I cannot answer that this minute. I will supply you with it as soon as I can go back to my office.

Mrs. GRIFFITHS. I think he should; do you not?

Mr. PLAPINGER. Yes.

Mr. BLATNIK. Here is another example, on page 15 of that same booklet, Dr. Irish, the ad showing Ipana toothpaste. In the ad, the ad states: "Ipana with WD–9 is good." So the question is, "What is so wonderful about WD–9?" The answer, "WD–9 is a powerful decay fighter."

The testimony by the representatives of the dental association state that WD–9 is the firm's name for sodium lauroyl sulfate, a type of synthetic detergent that is employed in several toothpastes as a foaming agent. It does have some antibacterial activity.

What would make that a "powerful decay fighter"? Any soap will have a mild, perhaps even a fair bit of antibacterial quality to it. Are these not wild statements?

Is it much of a problem to tell these people, look, at least on these major things, these gross misconceptions are being spread around the country?

Is that difficult, to just say, "Look, stop fooling the people"?

You say this is the best cleaning agent, WD–9 is the super cleaning agent; that is different. But to call it a "powerful decay fighter," there is nothing scientific about the statement. There is no scientific evidence available above a ninth-grade biology student to support that claim.

It should not be any more difficult to disprove that claim than it is to just make it without any substantiation.

Mr. GWYNNE. I was just going to ask, Will the man who gave the testimony that that is a false statement come down and, if we bring a complaint there, will he appear before the hearing examiner and take oath and say that is absolutely false? Would he say, "I know it and I have scientific proof to prove it"?

Mr. PLAPINGER. I do not think we can answer that question but I think we can say that gentleman is available to come down and discuss this issue with you.

Mr. GWYNNE. I think it would be very well if he would.

Mr. PLAPINGER. Judge Gwynne, getting back to this Cigarette Advertising Guide where you say that no representation shall be made when it has not been established by competent scientific proof applicable at the time of dissemination that the claim is true.

When you refer to the proof that the claim is true, you are not saying that you have to prove that the claim is untrue?

In other words this guide would seem to be shifting the burden of proof to the advertiser.

Mr. GWYNNE. No; there is no possible way that the Federal Trade Commission can change or write the law over.

Mr. PLAPINGER. I understand.

Mr. GWYNNE. Shift the burden anywhere.

Now, what that means is this: we lay down these guides and if the Federal Trade Commission staff run across a statement made by cigarette manufacturers which is contrary to the scientific proof as it, the Federal Trade Commission, knows it, then that should be challenged.

Is that not what it means?

Mr. BABCOCK. May I supplement that?

Mr. GWYNNE. Yes.

Mr. BABCOCK. Since you are interested in that, that rule is based on the Federal Trade Commission decision against P. Lorillard Co. circuit court of appeals. They republished an article appearing in the Reader's Digest some years ago in which it was claimed by a reliable test the Lorillard Old Gold cigarette, I believe, had less injurious ingredients. The court said on the showing we made there that the differences between the several cigarettes tested and compared were so insignificant that they had no significance in point of health or beneficial effect to be expected from smoking that cigarette as against the other. So having accomplished that much, that is incorporated into that rule, that you cannot claim a superior or better cigarette unless it has a "significant difference" in terms of health.

Now, you see, you will not see the words "in terms of health" there. We finally left that out, but it is really in there anyway.

Mr. PLAPINGER. You say "if the claim is true." That is stated in this guide.

Mr. BABCOCK. Then we would like to have that company rewarded for making a contribution. It is contributing something to the health of the smoker if it is a "significant difference" in terms of health.

Mr. PLAPINGER. It has to be true?

Mr. BABCOCK. That rule, controversial as it is, goes back to that decision and is related to it, and was our effort to translate it into something that we could use.

Now, as the judge properly points out, they come forward and say, "What we said is true and here is the proof of it. Here are the checks." Now we are up against the problem that we have repeated here, said here several times—and there is no magic in repetition—

we are now confronted with disproving it and moving in with clinical and scientific evidence which, as you know, we are working on. But we have not gotten that.

If we get this standard, we then can use it ourselves; and having recognition throughout the trade and throughout the laboratories, we will be in a position to test against their test and perhaps, I hope, prevail if they are not telling us the truth. But still they can use other tests if they want to in fighting us. They are not bound by this rule.

That would be our approach to it. They can still produce the scientific proof and evidence through any other device in addition to the use of our formula.

Mr. PLAPINGER. I appreciate that.

Mr. BABCOCK. When, as, and if we adopt it.

Mr. PLAPINGER. My only question here was it looked as if—and it still looks as if the claim must be proved scientifically before it can be accepted; not disproved scientifically by the FTC before it can be challenged.

Mr. BABCOCK. It worked for 4 years. I mean they have served it for the period mentioned in this statement. And in those years you saw nothing of this sort. Then, as we pointed out to you, it broke out in the case of the Lorillard people who again said, "We have done what you say we must do, we have developed the scientific difference, and we have a right to publish that." And the Kent cigarettes went to the top on that in point of sales.

Mrs. GRIFFITHS. Mr. Chairman.

Mr. BABCOCK. Now everyone else is doing it.

Mr. BLATNIK. Mrs. Griffiths.

Mrs. GRIFFITHS. Do you have the authority or would you need more authority to require, for instance, the cigarette company to print on the package the amount of tars and nicotines that a person would have in his lungs if he smoked the cigarette?

Mr. BABCOCK. In my judgment we do not have that.

Mrs. GRIFFITHS. You do not have the authority.

As a matter of fact when these cigarette companies advertise that filters are filtering out tar and nicotine, it does not really mean anything unless it is filtering out sufficiently that, under normal circumstances, a person, no matter how much he smoked, would get less tar and nicotine than he would have gotten in one package per day of the old cigarettes; right?

Mr. BABCOCK. That is right.

Mrs. GRIFFITHS. So it does not mean a thing to your health. It still increases his chance of death.

Mr. BABCOCK. Yes, this test is applicable only against comparisons with other cigarettes; otherwise you have nothing to compare against. Against your own? You cannot do that.

The test is only to use against competitors.

Mrs. GRIFFITHS. The only way—I mean all you have to prove to stop Viceroy is to prove there are other cigarettes with more filters, and so forth and so on.

Mr. BABCOCK. On the claim, yes.

Mrs. GRIFFITHS. That does not protect the public, does it?

Mr. BABCOCK. My answer to that, Mrs. Congresswoman, would be no, it does not.

Mrs. GRIFFITHS. Of course it does not. So that you really, in this case of the cigarettes, actually need more authority to protect the public? You need a better law?

Mr. BABCOCK. What protection are we aiming at?

Mrs. GRIFFITHS. Well, you need something that reduces this terrible death toll. If the chance of a person smoking more than one package of cigarettes per day increases his chance of dying by lung cancer 10 to 1, 10 times more than that of the average population, then it seems to me that you need a better law.

Mr. BABCOCK. The Public Health Service as I understand it is widely circularizing and informing the public that excessive smoking of cigarettes tends to increase the incident of cancer, particularly in the lungs.

Mrs. GRIFFITHS. Now we will not let people sell poison for use without prescription.

Mr. BABCOCK. No.

Mr. GWYNNE. I wonder if I could ask Mrs. Griffiths the question, what law would you suggest? Prohibit cigarettes?

Mrs. GRIFFITHS. I am asking you to suggest one, sir.

I am asking you first if you need one, and then I will ask you to suggest it.

Mr. GWYNNE. Well, I would be glad to answer that.

The whole trouble here with these claims that my cigarette is better than yours and all that kind of business, they can make those claims because they are all using a different test. It would be like trying a lawsuit involving how many acres were in a farm when there is no standard test of how big an acre is.

Mrs. GRIFFITHS. I agree with you.

Mr. GWYNNE. Now that is the whole purpose of what we have been doing, to get established a standard and useful and recognized test that everybody will take.

Now, we have reason to believe that when we establish that that many cigarette companies will use it. If it should be generally accepted by the industry and someone did not accept it, I think that would be a telling point with the court to say that that is a reasonable test and we are going to enforce it.

Now, you mentioned this, and I know you have discussed that here before, Mr. Chairman——

Mr. PLAPINGER. Excuse me, Judge.

Are you suggesting that there is no need for legislation to permit the FTC to prescribe testing standards?

Mr. GWYNNE. Well, it has not developed yet and I doubt if it will.

Mr. PLAPINGER. What has not developed, sir?

Mr. GWYNNE. Well, we have not yet established these standards.

Mr. PLAPINGER. But you could establish the standard without legislation; is that what you are suggesting?

Mr. GWYNNE. No. No, here is what I am suggesting. By dealing with experts in the field, if we could get their statement that this is a standard and sensible, and a generally accepted method in the industry of testing for tars and nicotine, we have reason to believe most of them will accept it.

Mr. PLAPINGER. So that it would not require legislation?

That is the point I am trying to determine.

Mr. GWYNNE. Well, I am just——

Mr. PLAPINGER. If this reasonable standard can be set up, you think——

Mr. GWYNNE. And accepted.

Mr. PLAPINGER. You think such tests would be acceptable by the courts, and that it would not require legislative authority for you to prescribe a test?

Mr. GWYNNE. I cannot guarantee what courts will do but we do know courts have often said that. We have had it in what are known as the feather cases; the question was how do you make these tests, and so forth. The court relied upon the fact that the preponderant share of the industry accepted as reasonable and proper certain tests and they said "that satisfies us it is reasonable." However, I would say if the courts do not take that view, then some law—and I know you have considered that and I think it is worthy of consideration frankly, Mr. Chairman—requiring the amount of tar and nicotine to be put on a package might be considered.

I am just giving my own view now. It is worthy of your further consideration. But because we do it, we do it on liquor—you know when you buy liquor——

Mr. BLATNIK. You know exactly what proof.

Mrs. GRIFFITHS. And you know what medicine is.

Mr. GWYNNE. You know all through. Now, the cigarette people themselves have made this tar and nicotine business interesting to the consumer, have they not? They have advertised it; that that is important to your health. Whether it is true or false, they have made the people think that. Now, therefore, if it is important, it is important that some sound sensible way can be arrived at, either by the courts and the Commission or by the Congress, so that everybody knows exactly what he is getting.

Mr. BLATNIK. Would it help, Judge Gwynne, in the case of cigarettes if the cigarette companies, instead of going to all the expense to say "This gives you less tar and nicotine," merely says, "Each cigarette contains not more than 15 milligrams of tar and not more than, say, 2 milligrams of nicotine"?

Mr. GWYNNE. I would like to make it clear, Mr. Chairman——

Mr. BLATNIK. Would that help?

Mr. GWYNNE. Well, what I say about the discussions you have been having about marking on the package—I am not necessarily stating the Commission's view; I have not obtained their opinion; I am just stating personally that I think you have got something there that might well be explored.

Mr. BLATNIK. Anyone could tell whether he had one more or less. One would have 17 milligrams of tar, another cigarette would have 22, another 14. Just see the amount.

Mr. GWYNNE. It all depends, of course—whether we do it or whether you do it by statute, it all depends, of course, on arriving at a proper standard.

Well, you have already passed laws like that.

Mr. BLATNIK. In a cigarette, there is only so much nicotine and tar. There is no difficulty to determine that; there are only so many milligrams.

Mr. GWYNNE. It depends on how you test it, Mr. Chairman.

They tell me you can test the same cigarette by varying methods and get a different answer. If you had a standard method of procedure, then you should get the same answer.

Mr. BLATNIK. If you buy ordinary table salt, you find this thing has so many ounces of salt, so many ounces of sulfate, so many grams of inert substance—way down to point zero, zero, zero, to three places. All of these rather inconsequential products make the effort to tell you exactly what is in them.

Mr. GWYNNE. When Congress passed the Flammable Fabric Act, if you remember, they wanted to establish certain standards of flammability. So in that act, if you recall, you authorized the Department of Commerce to set up standards to experiment and set up definite standards.

You can do the same with cigarettes; you can do it yourselves.

You probably would want, because of the change being made all the time, to delegate that authority to some department, such as—oh, Commerce or Agriculture.

Mrs. GRIFFITHS. Well, do you have the authority now to require that they put it on or——

Mr. GWYNNE. No.

Mrs. GRIFFITHS. Does Pure Food and Drug have such authority?

Mr. GWYNNE. Well, no—now wait a minute.

How much authority do they have over cigarettes? They do not have any authority over cigarettes unless it is a drug, do they?

Mr. BLATNIK. None at all.

Mr. PLAPINGER. Apropos of that, Judge, about the Food and Drug not having jurisdiction over tobacco, I wondered about your statement on page 21. You say you would—

> like to point out at this time that no Government agency, including the Food and Drug Administration, is making tests of the content of the smoke o. cigarettes.

I just wondered what the import of that statement was since they do not have jurisdiction?

Mr. GWYNNE. I think I should say this, of course in connection with dentifrices as I understand it, Dr. Irish, Food and Drug would have jurisdiction there if they made therapeutic claims; is that right? Drug claims?

Mr. IRISH. In the labeling, yes.

Mr. GWYNNE. And I would expect with cigarettes they would do that.

Mr. KINTNER. Wait a minute. We tried to convince the court that tobacco was a drug and the court refused to adhere to that view.

Mr. PLAPINGER. Right. I recall that. And that is the reason I asked the question why the insertion of the Food and Drug Administration at this point.

Mr. KINTNER. That was a matter of surveying the Government to determine whether testing equipment existed in any Government agency. The Commission found that this testing equipment was not available in any Government agency or department.

Mr. PLAPINGER. You are not meaning to imply any legal authority in the Food and Drug Administration to——

Mr. KINTNER. Not at all.

Mr. GWYNNE. Cigarette advertises drug quality, then what?

Mr. PLAPINGER. Then could it become a "device" under your act?

Mr. BABCOCK. What we tried to do, if I may say so, is to invoke the authority given us under the Wheeler-Lee amendment where under dangerous drugs or cosmetics we could go in.

We lost that case in the Second Circuit Court of Appeals. It was not a drug.

Mrs. GRIFFITHS. When did you try it?

Mr. BABCOCK. A couple of years ago; 1952, they tell me.

Mr. KINTNER. Six years.

Mr. BABCOCK. Now, you remember the discussion at this table last year as to whether or not you could perhaps assist the situation? And while the chairman is here, I am not suggesting that foods, drugs, cosmetics, and cigarettes—put them in that category, where we would have the power to go in and seek an injunction in relation to some health claim. Only with respect to some health claim could we employ it under the theory of that amendment.

Mrs. GRIFFITHS. Good suggestion.

Mr. PLAPINGER. That was a point involved in the Phillip Morris injunction, because this was not a drug.

Mr. BABCOCK. I do not advance that as a suggestion, but I remind you we discussed that last year at this table.

Mrs. GRIFFITHS. Yes.

Mr. PLAPINGER. May I ask a question with respect to dentifrices? On page 19, when you say:

> Since the fall of 1957, the Bureau of Consultation has asked each and every advertiser to submit "competent scientific proof" to justify its claims—

has this been done with dentifrices?

Mr. GWYNNE. Let me ask the Bureau of Consultation.

How about that?

Mr. JAMARIK. No, sir; we have not done that because we have no guides under which we would have the seeming authority to request that information.

Mr. PLAPINGER. You would not think it would be worthwhile in trying to check the advertised claims against the so-called scientific evidence?

Mr. JAMARIK. I think we will get back to that which we have been batting around this morning: a voluntary guide is of no value unless you can enforce it.

Mr. PLAPINGER. Absent the voluntary guide, I am just talking about measuring the advertised claim against the so-called scientific proof of the claim.

Mr. JAMARIK. Well, we certainly could. But if the party does not voluntarily correct his advertising, then we are at an impasse and the tendency is, of course, to lose respect.

Mr. PLAPINGER. You might have basis for enforcing it.

Mr. JAMARIK. That is right.

Mr. PLAPINGER. I do not have anything further.

Mr. BLATNIK. Judge Gwynne, I agree with you, I am sympathetic to the broad range, the whole spectrum of various fields with which the Commission has to work—the great problems, complex problems, legal problems, problems of evidence, scientific problems—I realize all of that. But here is what puzzles me, and I am sure puzzles many people, about the Federal Government's responsibility in protecting the consumer. Somehow or other on some substances—let's take canned tomatoes—procedures are quite strict. If there is 2 or

3 percent too much water in there, you confiscate the whole consignment, the whole lot, do you not? Or some agency does, perhaps Food and Drug.

Mr. BABCOCK. Food and Drug.

Mr. BLATNIK. Say you have 2 percent more water than you should. A tomato to begin with is 98 percent water if not more; 2 percent or more of water would not hurt the people.

Here we have no idea how many milligrams of tar and nicotine are in a cigarette, of which the majority of the smokers feel there is something harmful about. They need protection and are willing to pay more money for it.

We have this rather ridiculous situation of 5 or 6 cigarette manufacturers claiming to have "less tar than any other brand." No one knows who is lying. We do not on the committee. Apparently the Commission people do not.

If we do not know, how are the people to choose?

Mr. GWYNNE. Well, we have hopes, Mr. Chairman, as I told you, when we arrive at our conclusion as to these various tests that are now being taken, that we will be able to arrive at an acceptable standard which is being so generally accepted that then the people will know.

However, I do not know whether that is going to work out or not. You could easily—not easily, but I mean Congress could certainly provide for standards and for marking.

You talk about food and drug. The difference I think, Mr. Chairman, is years ago, many years before you were born, Congress began working on that problem of food and drug, did they not? And they have been working at it and have more or less solved it. They have not worked on it and solved it in connection with cigarettes. That is about the answer I think.

Mr. BLATNIK. It bothers me that the Government does make a very rigid and strict effort to enforce compliance in the case of something relatively harmless, in the case of canned tomatoes whether water content is too high or too low; and we make almost no effort on something that is of much greater seriousness and much more important to the health of the public, as cigarettes.

Mr. GWYNNE. I think the interest your committee has shown in this is commendable. Without undertaking to agree with some of the things that you may suggest, at least you have got the people—everybody—thinking.

Mr. BLATNIK. I get a little frustrated when we talk about this modern age of technology and accelerated training of scientists, spread more sound scientific knowledge, going into the complex business of knowing what is going on in the very heart of the atom—then we have this "bunko junk" peddled every 2 or 3 minutes wherever the TV station is operated, wherever the newspapers and magazines reach, making these ridiculous claims that, repeatedly, are going to have some affect; no matter how ridiculous the statement you make, if it is repeated long enough, chances are most people come to believe it and accept it as a fact.

I do not mean to be lecturing, I am merely trying to express some of the things that bother me. But in the case of dentifrices, we spend more in promoting misleading information on the care of teeth through the advertising of many of these questionable claims than we do as a society in spending for research to learn what the real causes of decay are, what possible methods there may be of either preventing or delaying or minimizing decay.

It is not a very national behavior when you think of the society, thinking of the Government, the people and our responsibilities to the people.

Mr. BABCOCK. Mr. Chairman, I would like to make one observation, not intending to be the Devil's advocate.

I checked the other day to see if we had ever received a complaint alleging the use of any dentifrice had had a harmful effect, and our records do not show any one such effect.

Mr. PLAPINGER. The point of the American Dental Association was the advertising discourages good dental hygiene.

Mr. BABCOCK. No harmful effect, which is important to me.

Mr. PLAPINGER. You might find more cavities.

Mr. BABCOCK. In relation to public interest.

Mr. PLAPINGER. After all, the care of the teeth is in the realm of unanimous public interest I would think.

But may I ask a question, Judge Gynne. On page 29, you refer to the fact that in 1918 the Commission had 689 people on its staff.

Correct me if I am wrong, but my impression was that during World War I, the Commission was given special duties in connection with warwork and, as a result, they had to take on additional staff.

Are you familiar with that situation, sir, by any chance?

Mr. GWYNNE. Well, I do not have the complete figures. However, we could give them to you year by year.

That probably is true, that probably explains that figure in part.

As a matter of fact, I think in 1914 or 1915 when the Commission opened its doors, they had about—what did they have at that time?

Mr. BABCOCK. I could not answer that.

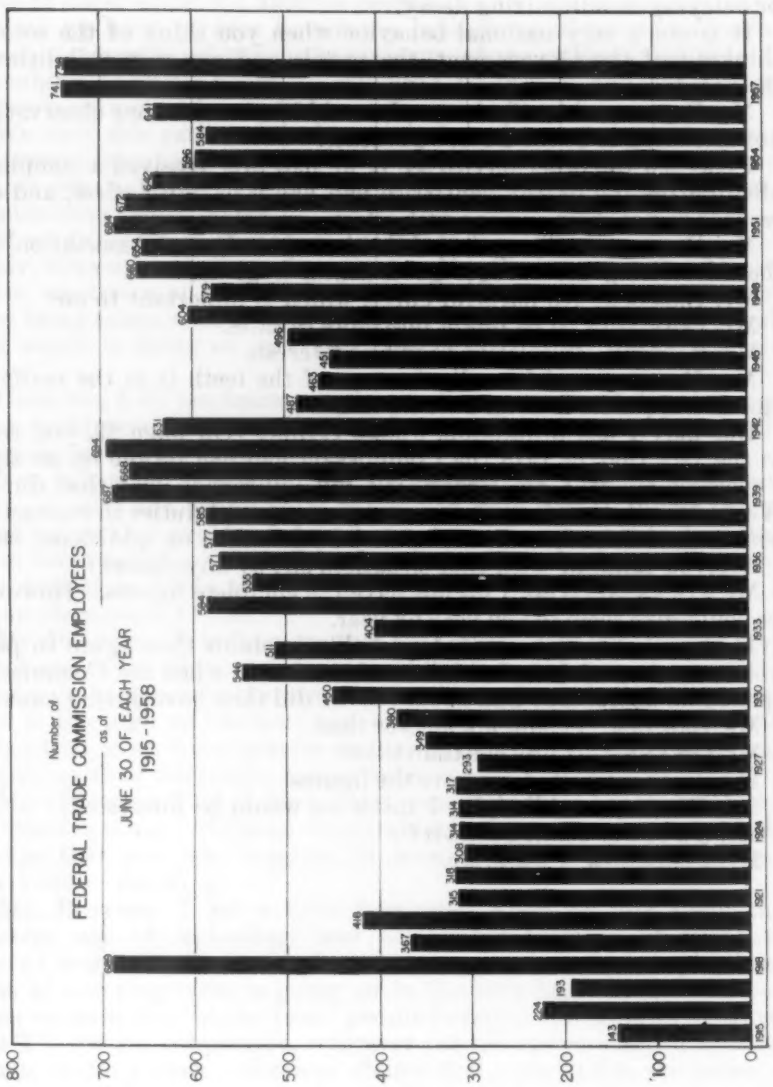
Mr. GWYNNE. It was less than that.

If you are interested, we have the figures.

Mr. PLAPINGER. All right, I think we would be interested.

Mr. GWYNNE. Shall I send it?

Mr. PLAPINGER. Please, sir.


Number of
FEDERAL TRADE COMMISSION EMPLOYEES
as of
JUNE 30 OF EACH YEAR
1915-1958
800
700
600
500
400
300
200
100
0
741
728
1957
641
594
594
1954
626
627
624
1951
630
624
624
1948
496
451
463
487
1945
631
694
668
687
1942
585
577
571
535
1939
584
404
511
546
1936
450
330
329
1933
293
317
314
304
308
316
315
1930
448
387
1927
1924
1921
1918
193
224
143
1915

Mr. Gwynne, yesterday the American Dental Association referred to the lack of facilities of the contract, and you allude to it here, about the number of statutes, the total amount of business under the jurisdiction of the Federal Trade Commission, and the total advertising today as contrasted with when you started. Now, have you ever asked for sufficient funds to provide a staff commensurate with this increased responsibility?

I am familiar with the fact that you requested $25,000 additional this year for scientific clinical testing facilities or to pay for clinical testing; I believe it was turned down. But has the Commission ever presented to the Congress a budget or to the Bureau of the Budget a request for sufficient moneys to adequately discharge your statutory responsibilities in all of these bills?

Mr. GWYNNE. I do not really suppose they have.

General Counsel calls attention to the fact we do not usually get what we ask.

I must say this, however, to do justice to the Congress, that in the last several years——

Mr. PLAPINGER. Excuse me, sir. You have to go to the Bureau of the Budget for your budgetary requests? Is that correct?

Mr. GWYNNE. Oh, yes.

Mr. PLAPINGER. How do you fare at the hands of the Bureau of the Budget before you get to the Congress?

Mr. GWYNNE. Oh, I think we have most years, since I have been Chairman—I remember one year was an exception. The Bureau of the Budget granted us more money than the Congress. Is that not right?

Mr. BABCOCK. We asked for more this year. The Budget allowed us more than the Congress did.

Mr. PLAPINGER. Did Budget ever approve more than you asked for?

Mr. GWYNNE. Not in my day. [Laughter.]

I remember one year we got——

Mr. PLAPINGER. Incidentally, Judge, I think that it would be of great interest to the committee if this information can be assembled without too much trouble, a history, tabular history, say, for the last 6 years or the last 7 years of the budgetary request by the FTC to the Bureau of the Budget, what happened to it there, and then the Congress and what happened to it there.

(The information is as follows:)

FEDERAL TRADE COMMISSION,
Washington, July 18, 1958.

MR. JEROME S. PLAPINGER,
Counsel, Legal and Monetary, Affairs Subcommittee, Committee on Government Operations, House of Representatives, Washington, D. C.

DEAR MR. PLAPINGER: In agreement with your request conveyed to me during the course of the hearing this morning I am pleased to enclose a summary statement of the Commission's requests for appropriations for fiscal years 1946–59.

I am aware that this extends over a longer period than you requested, but since it includes the information which you asked for I am sending it in the form in which we have had it prepared for other purposes.

Thank you for the courtesies extended this morning, and if there is any other way in which I can assist you please let me know.

With kind regards.

Sincerely yours,

HARRY A. BABCOCK,
Executive Director.

Summary of budegt requests to the Bureau of the Budget, to Congress, and appropriations, fiscal years 1946–59

Fiscal year		Requested by Commission	Allowance by Budget Bureau	Appropriated by Congress
1946	Lump sum	$3,357,035	$1,948,000	$1,897,833
	Printing and binding	80,900	44,000	44,000
	Total, 1946	3,437,935	1,992,000	1,941,833
1947	Lump sum	3,480,623	2,573,000	2,194,120
	Printing and binding	91,600	46,400	45,000
	Supplemental	1,536,209	850,000	325,000
	Printing and binding	7,000	7,000	5,000
	Pay Act	281,000	281,000	281,000
	Total, 1947	5,396,432	3,757,400	2,850,120
1948	Lump sum	4,989,254	3,920,700	2,900,120
	Printing and binding	86,825	57,300	55,000
	Total, 1948	5,076,079	3,978,000	2,955,120
1949	Lump sum	4,730,586	3,920,000	3,401,510
	Supplemental:			
	Antitrust	1,100,000		
	Insurance	200,000		
	Printing and binding	158,680	55,000	46,525
	Pay Act	173,000	173,000	173,000
	Total, 1949	6,362,266	4,148,000	3,621,035
1950	Lump sum	5,900,500	3,692,000	3,650,000
	Printing and binding	87,750	47,000	
	Pay Act	88,300	83,000	73,000
	Supplemental: Trends in Economic Concentration	94,886		
	Total, 1950	6,171,436	3,822,000	3,723,000
1951	Lump sum	5,392,700	4,225,000	3,891,695
1952	Lump sum	5,883,000	3,892,000	3,940,400
	Supplemental:			
	Sec. 7	950,000	500,000	
	Wool	25,000		
	Sec. 7	737,500	300,000	100,000
	Pay raise	331,000	274,000	274,000
	Total, 1952	7,926,500	4,966,000	4,314,400
1953	Lump sum	6,437,235	4,367,000	4,053,800
	Supplemental (sec. 7)	600,000	300,000	125,000
	Total, 1953	7,037,235	4,667,000	4,178,800
1954	Lump sum	7,069,800	5,500,000	4,053,800
1955	do	5,521,000	4,200,000	4,045,000
	Supplemental (pay raise)	84,000	84,000	84,000
	Total, 1955	5,605,000	4,284,000	4,129,000
1956	Lump sum	5,368,900	4,300,000	4,262,500
	Supplemental (pay raise)	286,000	286,000	286,000
	Total, 1956	5,654,900	4,586,000	4,548,500
1957	Lump sum	6,087,500	5,500,000	5,550,000
1958	do	6,372,000	6,250,000	5,950,000
1959	do	6,077,000	6,025,000	

Mrs. GRIFFITHS. Better make it 10 years, bipartisan.

Mrs. GWYNNE. We can get that; sure, we will get that.

Mr. BABCOCK. Are we being asked by Congress?

Mr. PLAPINGER. Pardon?

Mr. BABCOCK. Are there not some regulations with respect to it? I think the Chairman is right; we can supply them to you.

Mr. PLAPINGER. This is information we receive from other departments that are under our jurisdiction.

Mr. BABCOCK. If it is proper, it would be no trouble at all. We will be pleased to give it to you. It will not take long at all.

Mr. KINTNER. The general past history is we usually ask the Bureau of the Budget for more money than they are willing to grant, and more often than not the Congress cuts us from the Bureau of the Budget approval, so——

Mr. PLAPINGER. The real question here is whether you have ever asked for sufficient moneys so that in your own mind this would take care of doing the job the way you want to do the job.

Mr. GWYNNE. There are a couple of problems there; I would like to suggest this: No amount of money that Congress has ever given or ever will give, or ever could give, will ever insure that every single law violation in our domain would be taken care of, any more than you can ever get enough money, or the States cannot, to take care of all the crime. So in any event there has got to be a lot of discretion used as to how it can be used.

It has been my conviction—I have said so when I was in Congress and I have said so since I have been on the Commission—that the country has not given sufficient money for the type of work we have been considering here this morning. I mean both the Budget and the Congress.

Mrs. GRIFFITHS. Well, a lot more could be done than is now being done. It is not exactly like murder. You cannot have a policeman for every single person and a policeman for the policeman. But in the cases that you are supervising, it takes a lot of work on the part of the person that is evading the law to do the evasion. Time elapses. You have a fairly good chance to catch him.

Now I will admit I do not think you are going to stop it all. But I really feel that the Federal Trade Commission and Food and Drug Administration have been starved by lack of funds.

We make a gesture as if we really believed that these laws are going to be enforced. It is a very cynical gesture because we do not give you enough money to do it if you want to do it.

Mr. GWYNNE. I would like to add this, too, Mrs. Griffiths, we have been giving a lot of emphasis now to, you might say, the cooperative part of it. A lot of the trouble is due to the fact that industry does not know what it should do, or they do it because some competitor is doing it

We have been trying so far as possible to operate things on an industrywide basis and I think it will bear fruit as the years go by.

It will have to be backed up, of course, with an iron hand in some cases; but what you say is all too true, I regret to say.

Mr. BLATNIK. No further questions.

Mr. PLAPINGER. Mr. Chairman, as has been the practice in the past, permission is requested for the counsel or the staff to insert exhibits at appropriate places in the record?

Mr. BLATNIK. Without objection, so ordered.

Mr. PLAPINGER. Also may I suggest in view of the fact that we have hearings next week scheduled on another topic and there have been references to a number of products by the American Dental Association, and there were also some specific references this morning—that we permit the record to remain open for 2 weeks in order to permit the companies whose products were referred to or anybody else interested to file statements for the record. (See appendix, exhibit 2, p. 112, and exhibit 9, p. 221.)

Mr. BLATNIK. That has been done in the past and, without objection, so ordered.

Again, Judge Gwynne, thank you and your associates.

The hearings are adjourned.

Meeting is adjourned.

(Whereupon, at 12: 15 p. m., the subcommittee adjourned.)

APPENDIX

EXHIBIT 1

[The Journal of the American Dental Association, May 1957]

CARIES-INHIBITING VALUE OF A DENTIFRICE CONTAINING STANNOUS FLUORIDE; FIRST YEAR REPORT OF A SUPERVISED TOOTHBRUSHING STUDY

William A. Jordan,[1] D. D. S., M. P. H., and

John K. Peterson,[2] D. D. S., M. P H., Minneapolis

The possible value of stannous fluoride as an anticariogenic agent has been studied for some time. It has been shown to be more effective than sodium fluoride for reducing enamel solubility *in vitro*,[3,4] for reducing dental caries in rats[5-7] and hamsters,[8] and for reducing dental caries in children after topical treatment.[9-11] Moreover, stannous fluoride combined with a compatible abrasive (calcium pyrophosphate) in a dentifrice has already shown an encouraging effectiveness in decreasing dental caries in children and adults.[12-15] Additional clinical studies are needed to verify the results of the dentifrice studies by Muhler and associates. The clinical evaluation study at Bloomington, Minn., has been set up to obtain more information concerning the value of a stannous fluoride-containing dentifrice.

PROCEDURE

Included in the study were 628 children who were in the third and fourth grades at the time of the initial examination in May 1955 and whose parents signed authorizations for participation. These children (ages 8 to 11) all re-

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[1] Chief, section of dental health, Minnesota Department of Health.

[2] Assistant chief, section of dental health, Minnesota Department of Health.

[3] Van Huysen, G., and Muhler, J. C. Enamel solubility reducing effect of flavored low concentration stannous flouride solution. J. D. Res. 27 : 46 Feb. 1948.

[4] Muhler, J. C., and Day, H. G. Relation of pH to the effectiveness of sodium fluoride and stannous fluoride in decreasing enamel solubility. J. D. Res. 31 : 102 Feb. 1952.

[5] Muhler, J. C., and Day, H. G. Effect of stannous fluoride, stannous chloride and sodium fluoride on the incidence of dental lesions in rats fed a caries-producing diet. J. A. D. A. 41 : 528 November 1950.

[6] Muhler, J. C., and Day, H. G. Effect of stannous fluoride in food and in drinking water on caries prevention in rats on high sucrose and coarse corn diets. J. Nutrition 44 : 413 July 1951.

[7] Muhler, J. C.; Nebergall, W. H., and Day, H. G. Preparations of stannous fluoride compared with sodium fluoride for the prevention of dental caries in the rat. J. A. D. A. 46 : 290 March 1953.

[8] Radike, A. W., and Muhler, J. C. Incidence of dental caries in hamsters receiving two different water-soluble fluorides at low concentrations. J. D. Res. 32 : 807 December 1953.

[9] Howell, C. L., and others. Effect of topically applied stannous fluoride on dental caries experience in children. J. A. D. A. 50 : 14 January 1955.

[10] Slack, G. L. Effect of topical application of stannous fluoride solution in the prevention of dental caries. J. D. Res. (Abst.) 34 : 785 October 1955.

[11] McLaren, H. R., and Brown, H. K. A study of the use of a topically applied stannous fluoride solution in the prevention of dental caries. Canadian J. Pub. Health 46 : 387 October 1955.

[12] Muhler, J. C., and others. The effect of a stannous fluoride-containing dentifrice on caries reduction in children. J. D. Res. 33 : 606 October 1954.

[13] Muhler, J. C.; Radike, A. W.; Nebergall, W. H., and Day, H. G. Effect of a stannous fluoride-containing dentifrice on caries reduction in children. II. Caries experience after one year. J. A. D. A. 50 : 163 February 1955.

[14] Huhler, J. C.; Radike, A. W.; Nebergall, W. H., and Day, H. G. The effect of a stannous fluoride-containing dentrifrice on dental caries in adults. J. D. Res. 35 : 49 February 1956.

[15] Muhler, J. C., and others. A comparison between the anticariogenic effects of dentifrices containing stannous fluoride and sodium fluoride. J. A. D. A. 51 : 556 November 1955.

ceived dental examinations by a single examiner with the aid of a portable dental chair, explorers, and a Burton mouth light. Each sound, carious, filled or missing permanent tooth and surface was recorded in code on an examination form designed for the base line and two subsequent examinations. (At the time of the second examination, the first year data on the form were masked to prevent possible unconscious examiner bias in diagnosing.) Two posterior and three anterior bitewing roentgenograms were taken of each child. Any carious surfaces which were subsequently found by the roentgenographic examination were added to the examination forms.

The dentifrice was supplied to the children in plain tubes, with only the label "E" or "H" appearing on the carton. The two dentifrices appeared to be identical in taste, consistency and appearance. They differed only in that one contained 0.4 per cent stannous fluoride and 1 per cent stannous pyrophosphate and had a pH of 4.9; the pH of the control paste was 6.8. The slightly soluble stannous pyrophosphate furnished a reservoir of stannous ions to replace those, derived from stannous fluoride, that may have been inactivated by reaction with other constituents of the formulation. Laboratory evidence [16] indicated that a pH of around 5.0 was most likely to be suitable from the standpoints of stability and effectiveness of stannous fluoride, but that this degree of acidity in a control dentifrice (without stannous fluoride) could introduce a real danger to dental enamel under usage conditions.

The identity of the dentifrice containing the stannous fluoride was unknown to the authors until after the first year anniversary examinations were completed. A sealed letter supplied by the manufacturer and stating the composition (Table 1) of the two dentifrices was opened after the completion of the examinations and the tabulation of data. These formulas are the same as those of the dentifrices tested previously [12-15] with the exception that the "H" dentifrice contained 1 per cent stannous pyrophosphate.

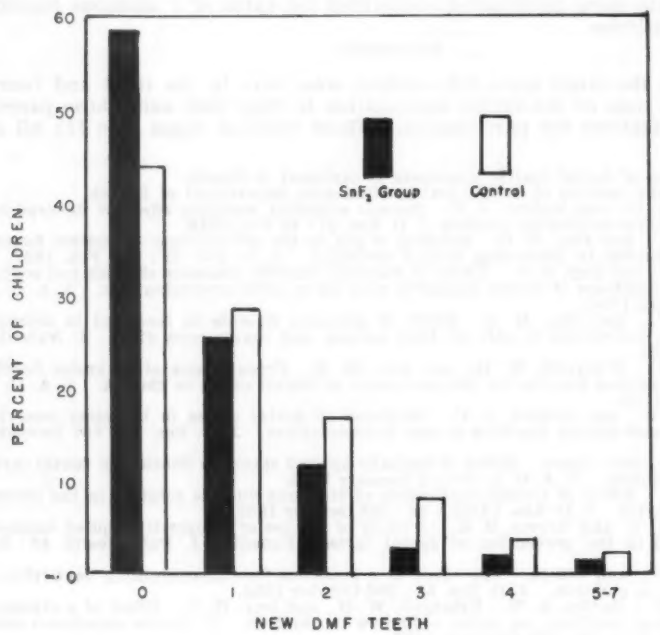


Fig. 1 • Percentage of children with 0-7 new DMF teeth

See footnotes 12–15 on page 107.
[16] Radike, A. W. Personal communication.

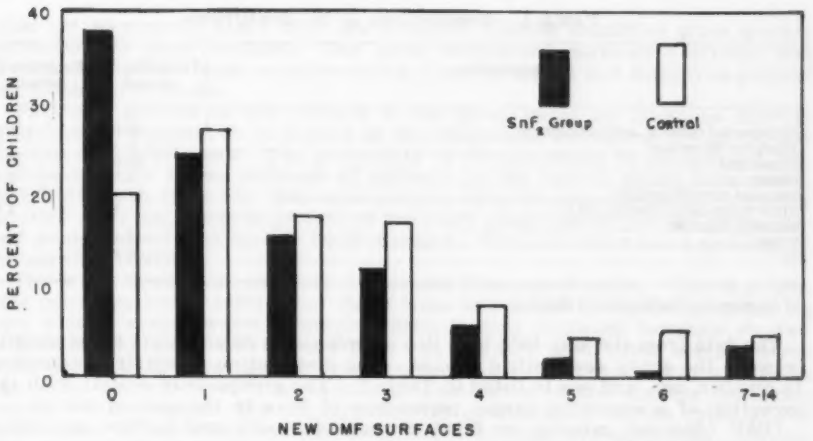


Fig. 2 • Percentage of children with 0-14 new DMF surfaces

The children at one school received the stannous fluoride dentifrice, whereas those at the other school received the control. The principals at the two schools selected the dentifrice for their schools by the flip of a coin. Each child was given a toothbrush and his designated dentifrice in May 1955 for summer use. More dentifrice was always available at the schools and the children were encouraged to take enough to supply their whole family. The children were shown the proper toothbrushing technic and encouraged to brush their teeth routinely after each meal at home. During the school year 1955–1956 they brushed their teeth under supervision once a day after the noon meal in school.

The relative effectiveness of the "E" and "H" dentifrices and consequently the dentifrice containing 0.4 percent stannous fluoride was measured by the comparative incidence of new carious teeth and tooth surfaces in the study and control children during the first year of the study.

A smaller group of children in two other Bloomington schools were included in another phase of the study. These children did not brush their teeth while in school. The children were paired according to caries prevalence, with each school having equal numbers of children using "E" and "H" dentifrice. Dentifrice and brushes were sent home with these children. This report does not include the data from these children because distribution procedures in these schools resulted in a possible exchange of dentifrice among an unknown number of children. Fewer than the expected number of new DMF teeth and surfaces appeared to develop in both the study and control groups. This is questionable and unmeasurable, however, because of the failure of a large number of roentgenograms taken during the last two days of the anniversary examinations.

COMPARABILITY OF STUDY GROUPS

Bloomington, Minn., is a rapidly expanding suburban community that has grown from 3,500 to 35,000 people in ten years. The large majority of the homes are less than ten years old and are in the 10 to 15 thousand dollar class. Consequently most of the children are from the same economic level and lead a similar way of life.

TABLE 1.—*Composition of the dentifrices*

Composition	Dentrifice E, percent	Dentrifice H, percent
Heat-treated calcium orthophosphate	40.00	39.00
Detergent (nonsoap)	1.51	1.51
Humectant	30.00	30.00
Bender	1.50	1.50
Stannous pyrophosphate		1.00
Minor ingredients (flavor, etc.)	1.44	1.62
Stannous fluoride		.40
Water	25.55	24.97
pH [1]	6.8	4.9

[1] As measured in 25 percent slurries.

The data from the May 1955 base line examinations demonstrate the similarity between the study and control groups. The distribution of children according to number, age, and sex is listed in Table 2. The groups were similar with the exception of a somewhat larger percentage of boys in the control school.

DMF (decayed, missing, or filled permanent) tooth and surface precalence was determined for each group. Since the relative number of children in each age group was the same for the study group and the control group, the data were grouped without age adjusting. Table 3 shows the similarity of DMF teeth and DMF surface data in the two groups. There was no statistical difference in caries prevalence in the two groups at the beginning of the study program.

There was a loss of 63 children (20 percent) in the study group and 60 children (19 percent) in the control group during the first year of the study. A comparison of the initial DMF prevalence of the remaining children showed no significant change from the original groups.

The amount of dentifrice used at home by the families of the study and control children was estimated in October 1955 by sending home a questionnaire at the beginning and end of the month. The families reported 0.34 tube of dentifrice used per person during October for the study group, and 0.36 tube per person for the control group. The difference is not significant, so the two groups were considered to use comparable amounts of the dentifrice.

RESULTS AND DISCUSSION

Table 4 shows the DMF teeth and DMF surface incidence that took place in the study (stannous fluoride) and control groups during the calendar year ending in May 1956. There were 35 percent fewer DMF teeth developed in the group using the stannous fluoride dentifrice than developed in the control group. When the DMF surfaces index is used as a method of comparison, the reduction for the group using the stannous fluoride dentifrice is 34 percent. Both these reductions are statistically significant as indicated by their low probabilities. These findings are similar to those reported by Muhler and coworkers [13-15] after one year of unsupervised use of a stannous fluoride dentrifrice.

TABLE 2.—*Distribution of children by age and sex, May 1955*

Age	Study group				Control group			
	Boys	Girls	Total	Percent of total	Boys	Girls	Total	Percent of total
8	62	73	135	43.4	83	58	141	44.5
9	62	61	123	39.5	67	58	125	39.4
10	26	24	50	16.1	28	20	48	15.1
11	2	1	3	1.0	2	1	3	.9
Total	152	159	311		180	137	317	
Percent of total	48.9	51.1			56.8	43.2		

There was a greater reduction in the incidence of caries on less susceptible surfaces (Table 5). The greatest reduction occurred on the buccolingual surfaces (41 percent) and the least on the occlusal surfaces (23 percent). This

does not necessarily mean that the stannous fluoride dentifrice gives greater protection to some surfaces. The more susceptible surfaces (occlusal and proximal) probably need more protection than the buccal and lingual to prevent the incidence of caries.

Fifty-nine percent of the children in the group using the stannous fluoride dentifrice, in contrast to 44 percent of the children in the control group, did not develop new DMF teeth. The probability of this occurring by chance is 0..001, Correspondingly larger numbers of children in the control group developed 1 to 7 DMF teeth (Fig. 1). The same pattern (Fig. 2) occurred in the incidence of DMF surfaces, where 38 percent of the study group and 20 percent of the control group did not develop new DMF surfaces. This difference has a probability of less than 0.0001.

The study dentifrice contained 0.4 percent stannous fluoride. This is a flouride concentration of 1,000 ppm. Each home and school in Bloomington has its own well to supply water. Samples taken in four scattered locations showed a flouride content of 0.09 to 0.11 ppm. In January 1956, urine samples were obtained from 40 boys in each group to determine if there was any change in the urine fluoride level from incidental swallowing of the fluoride dentifrice during toothbrushing. The average fluoride concentration in the urine of the boys using the stannous fluoride-containing dentifrice was 0.198 ppm, whereas the corresponding fluoride concentration from the boys using the stannous fluoride-free control dentifrice was 0.196 ppm. These concentrations were remarkably close, and indicate that there was no increase in the urinary fluoride level resulting from the use of the study dentifrice. These findings corroborate previous work by Schweinsberger and Muhler.[17]

TABLE 3.—*DMF teeth and surfaces: Initial examination*

Group	Number of children	Mean DMF teeth	Standard error	Mean DMF surfaces	Standard error
Study	248	3.67	0.125	6.20	0.267
Control	257	3.58	.129	6.24	.298

TABLE 4.—*Mean DMF incidence, May 1955–May 1956*

Group	Number of children	DMF teeth incidence		DMF surfaces incidence	
		Mean	Standard error	Mean	Standard error
Study ($Sn F_2$)	248	0.673	0.066	1.488	0.113
Control	257	1.043	.077	2.253	.134
Percent reduction			35.47		33.95
Probability			<.001		<.0001

TABLE 5.—*Mean DMF surfaces incidence, May 1955–May 1956*

	Number of children	Mean DMFS incidence			
		Proximal	Occlusal	Bucco-lingual	Total
Study group ($Sn F_2$)	248	0.762	0.403	0.323	1.488
Control group	257	1.187	.521	.545	2.253
Percent reduction		35.8	22.7	40.7	34.0
Probability		<.001	<.11	<.003	<.0001

[17] Schweinsberger, R. A., and Muhler, J. C. Urinary fluorine levels following the clinical use of a stannous fluoride-containing dentifrice (Abst.). J. D. Res. 34 : 726 Oct. 1955.

The prevalence of stained teeth in the children using both dentifrices was recorded at the time of the second examination. Forty children had noticeably stained teeth in the stannous fluoride group, and 45 were found with similar staining in the control group. This staining was typical of that found on surfaces that are not self-cleansing in mouths with poor oral hygiene. Casual observations rather than rigid criteria were used in diagnosing "stained teeth."

Five hundred and five, fourth and fifth grade children, equally divided between two elementary schools, provided the control and study groups for the clinical evaluation of a 0.4 percent stannous fluoride dentifrice. The children in both schools were comparable in age, sex, and caries prevalence. Children in both schools brushed their teeth once a day in school after the noon meal, and also received dentifrice and brushes for home care. A mid-year study determined that comparable amounts of dentifrice were being used at home by each group.

The children in the school who used the stannous fluoride-containing dentifrice developed 35 percent fewer DMF teeth and 34 percent fewer DMF surfaces than the control children during the first year of the study. These reductions are statistically significant.

A urinalysis in January 1956 showed no elevation in fluoride content in the group using the stannous fluoride-containing dentifrice when compared with the control.

No difference in the prevalence of stain was found in either the stannous fluoride or control group.

The first year results from the use of this stannous fluoride-containing dentifrice at Bloomington, Minn., corroborate the original work by Muhler and associates in Indiana and show the effectiveness and safety of stannous fluoride used in an abrasive-compatible dentifrice for one year.

EXHIBIT 2

THE PROCTER & GAMBLE CO.,
Cincinnati, Ohio, August 7, 1958

Hon. JOHN A. BLATNIK,
Chairman, Legal and Monetary Affairs Subcommittee,
Committee on Government Operations,
House Office Building, Washington, D. C.

DEAR SIR: Pursuant to your invitation extended at the close of the hearing before the Subcommittee on Legal and Monetary Affairs of the House Committee on Government Operations on July 18, 1958, we are pleased to attach a statement in reply to the testimony offered by the representatives of the American Dental Association.

It is our understanding that this statement will be included in the printed record of the hearings held by your subcommittee concerning dentifrice advertising. We are confident that the data presented herewith, together with that previously submitted to the subcommittee, completely supports the claims made in Crest and Gleem advertising.

Very truly yours,

WM. G. WERNER,
Director, Public and Legal Services.

Procter & Gamble appreciates the invitation of the Legal and Monetary Affairs Subcommittee of the Committee on Government Operations of the House of Representatives to submit comments on the July 17, 1958, testimony of the American Dental Association concerning dentifrice advertising. These comments will refer primarily to the statements made by the representatives of the ADA concerning the advertising of Procter & Gamble's two dentifrice products, Crest and Gleem.

At the outset, we will state for the record that Procter & Gamble has engaged in the manufacture and sale of household products—principally cleansing and food products—for 121 years. It has been in the toothpaste business since 1952. Its success in the fields in which it operates is based primarily on its ability to provide consumers with useful products of proven value at a low

price. Procter & Gamble's competence is founded upon its long experience and extensive research in product and process development, manufacturing, and marketing. Its research activities include the expansion of basic knowledge of skin, teeth, and hair; studies of every phase of product and process development; manufacturing and marketing techniques; and ultimately studies made by consumers in their own homes on product performance.

Procter & Gamble has been actively engaged in dentifrice research since 1928. Its specific research into the effective use of fluorides in dentifrices has been carried on since 1941. The staff working full time in Procter & Gamble's laboratories on dental research projects includes scientists with advanced degrees in dentistry, pharmacy, histology, physical chemistry, biochemistry and organic chemistry. Additionally, the company since 1941 has supported independent dental research efforts at five major universities.

From this background, we would like to comment on the statements of the ADA concerning Crest and Gleem advertising.

CREST

In its July 17 testimony, the ADA representatives had two basic criticisms of the advertising for Crest. They claimed:

1. That the headline 'Look, Mom—no cavities!" is misleading because, in their opinion, it promised 100 percent freedom from decay.
2. That the decay reduction claims in the advertising are inadequately supported since, in their opinion, only one research study, conducted by the Health Department of the State of Minnesota, is acceptable and even it showed a "tapering off" in Crest's effectiveness after 24 months of use.

Concerning these allegations, we present the following comments:

1. The impression that a person or group of persons gets from a specific printed advertisement or television commercial is necessarily subjective; it is very difficult to make an objective measurement of the meaning "most people" get from a given set of words and pictures. The fact that the above interpretation is not necessarily the only one emerges quite clearly from page 40 of the reporter's transcript of the July 17 hearings. In discussing the Crest advertisement shown to the subcommittee, Dr. Pearlman and Representative Meader got quite different impressions. Dr. Pearlman held that the headline in this advertisement promised "100 percent freedom from decay." Mr. Meader felt that "it just indicates that this boy is happy because he does not have any decay."

The words in the advertisement and the emphasis given them make Dr. Pearlman's interpretation difficult to support. In display type, next to the illustration of the product, is the statement that brushing with Crest will result in "far fewer cavities" or, in some versions of the advertisement, "far less decay." If we had any desire to "mislead" readers of this advertisement into thinking we were promising 100 percent protection, we would not have displayed this statement in juxtaposition to what is, from our point of view, the most important part of this advertisement—the name of the product being advertised.

Furthermore, the text of this advertisement refers specifically to "far less new decay"—a statement based upon clinical studies conducted independently by university and public-health scientists. Other advertisements contain actual decay reduction figures of 42 percent for adults and 49 percent for children.

2. The representatives of the American Dental Association's allegation that Crest claims for decay reduction are inadequately supported grows out of the refusal of the ADA to acknowledge the relevance of any of the clinical studies made during the development of Crest. It is their contention that the earlier studies should be completely disregarded because the product used in these studies is not precisely the product now on the market. Procter & Gamble's dental research staff disagrees with this view.

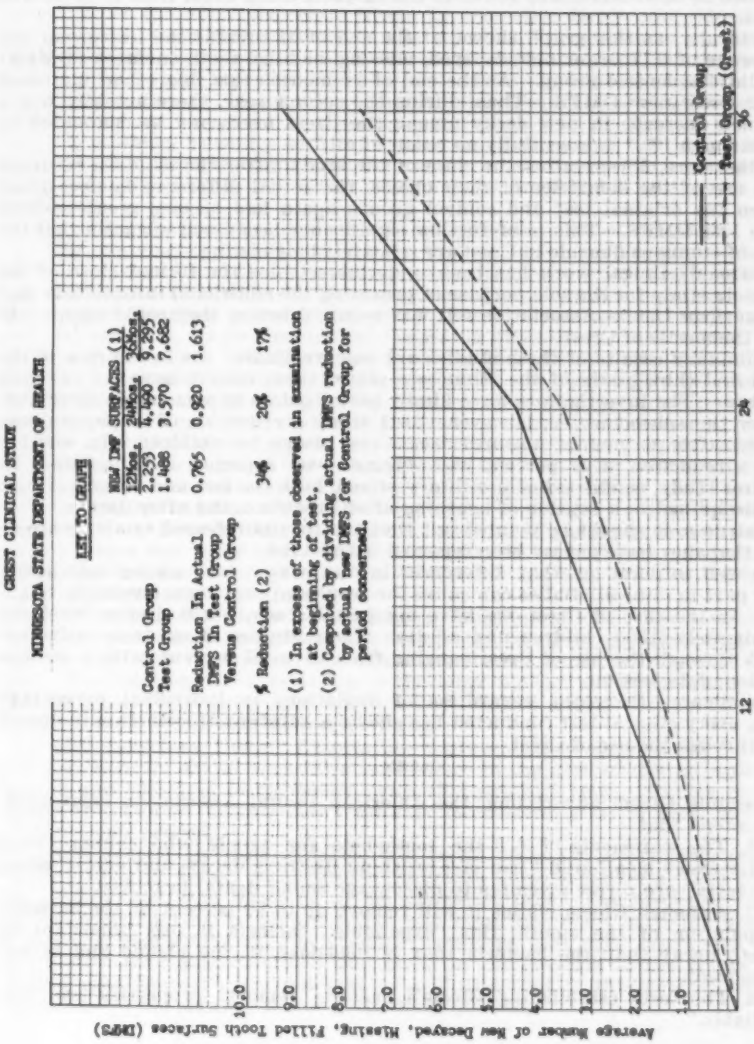
The development of Crest was accompanied, to the best of our knowledge, by the most detailed clinical research ever done in support of the effectiveness of a dentifrice. Dr. Pearlman acknowledged the extent of our research at several points in his testimony. The decay-reduction claims in Crest advertising are all based on this work.

Basic research projects on the effectiveness of stannous fluoride in reducing dental caries and its incorporation into a dentifrice were conducted at Indiana University under the direction of Drs. M. K. Hine, H. G. Day, J. C. Muhler, and W. H. Nebergall. This work was carried on with the assistance of grants from Procter & Gamble.

Subsequent to the development of the stannous fluoride dentifrice, later called Crest, and the indications of its effectiveness in the laboratories of both Indiana University and Procter & Gamble, clinical studies were initiated in 1952 at Indiana University. These studies, which proved the decay-reducing effectiveness of this toothpaste for both children and adults, have been reported in the leading dental journals—Journal of the American Dental Association and the Journal of Dental Research—beginning in 1954 and continuing through 1957. Reprints of these articles are attached to this statement as exhibits A, B, C, D, and E.

During the course of this clinical work, experimentation was also proceeding on the dentifrice in the Procter & Gamble laboratories. As must be expected with every new product, modifications designed to improve the consistency, stability, etc., of the product were made while it was in pilotplant stages and as it moved to large-scale production. At no time did any of these modifications alter the active ingredient (stannous fluoride), the polishing agent, or any other critical component. No modification of any kind was made without extensive laboratory testing to assure that the change did not affect the active ingredient in any way which would make the preceding clinical work inapplicable.

Despite our belief, supported by this laboratory testing, that the refined Crest product (the one being sold and advertised today) was as effective in reducing decay as the original products, the company desired to confirm these conclusions with an additional full-scale clinical study. This study was initiated by the Minnesota State Department of Health in 1955 and a report on the first year's results appeared in the May 1957 issue of the Journal of the American Dental Association (exhibit F attached). These results confirm the earlier findings by the Indiana University group and, in the judgment of our research staff, established as fact that no change had been made which would lessen Crest's effectiveness in preventing decay. Our dental research staff believes that the Minnesota research is not an isolated study, as contended by the ADA representatives, but is of significant value in confirming the earlier clinical work and a vital part of all of the work which has been done to establish the effectiveness of this product.


CREST CLINICAL STUDY
MINNESOTA STATE DEPARTMENT OF HEALTH
KEY TO GRAPH
NEW DMF SURFACES (1)
12Mos. 24Mos. 36Mos.
Control Group 2.253 4.490 6.895
Test Group 1.486 3.570 7.682
Reduction In Actual DMFS In Test Group Versus Control Group 0.765 0.920 1.613
% Reduction (2) 34% 20% 17%
(1) In excess of those observed in examination at beginning of test.
(2) Computed by dividing actual DMFS reduction by actual new DMFS for Control Group for period concerned.
Control Group
Test Group (Crest)
Average Number of New Decayed, Missing, Filled Tooth Surfaces (DMFS)
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
12
24
36
NUMBER OF MONTHS AFTER BEGINNING OF TEST

The testimony of the representatives of the ADA also suggested that the Minnesota study showed a lessening of the decay reducing effect of Crest during the second year of the test. Dr. Pearlman said "* * * during the second year there was essentially no result at all." A fair evaluation of the results shown on the attached chart does not lead to this conclusion. Although the "percent reduction" in decay within the test group (Crest users) versus he control group (non-fluoride-toothpaste users) declined from 34 percent at the end of 12 months to 20 percent at the end of 24 months, the actual number of new cavities continued to be substantially lower in the subjects using Crest than in those who did not.

Specifically, as this graph shows, at the end of 12 months the test group had an average of 0.77 fewer new decayed, missing, or filled tooth surfaces (DMFS) than did the control group. At the end of 24 months this figure had increased to 0.92 fewer new DMFS. Thus, during the second year, there actually was a continued decrease in new decay among the Crest users, not as contended by Dr. Pearlman "* * * essentially no result at all."

Furthermore, 1 year after the close of the study, after the children returned to the use of the dentifrice of their choice, the actual difference in new decay between the original test and control groups again had become greater—from 0.92 to 1.61 DMFS. This is of further significance because it suggests that the effects of stannous fluoride in Crest are relatively long lasting.

Additional clinical work has been undertaken since the formal close of the Minnesota study for the sole purpose of providing the additional information that the American Dental Association felt was required before they could adequately assess the merits of Crest.

Preliminary results of these studies are now available. As in the case of the second and third years of the Minnesota study, these results have not yet been published. The investigators have kindly permitted us to summarize their findings for the subcommittee, however. In 1 study a reduction of 23 percent was obtained after 6 months' unsupervised Crest usage by children. In another study, a reduction of 57 percent was obtained over a period of 10 months. In the latter study, conducted at a military school, both the test and control groups were disciplined to a routine of brushing after breakfast and after dinner.

In fairness, it should be pointed out that the results referred to above are so recent that they have not yet been reported to the ADA.

It is well to point out that differences in diet, water, etc., among individuals taking part in clinical studies can cause the results to vary from one study to another. In the case of Crest, we have not just 1 study, but 6 studies involving approximately 2,500 children and adults. These studies show decay-reduction benefits through the use of Crest ranging from 21 to 57 percent, with a median reduction of 38 percent.

In summary, therefore, regardless of variations in individual percentage results, every clinical test conducted has shown a substantial reduction in dental caries through the use of Crest.

GLEEM

Concerning Gleem advertising, the American Dental Association representatives contend that—

1. The statements "* * * the toothpaste for people who cannot brush after every meal" and "just one brushing destroys decay- and odor-causing bacteria" are direct attempts to discourage sound dental practices.

2. Although Gleem claims it will remove up to 90 percent of the bacteria population of the mouth, this "expellable" bacteria is less important in tooth decay than the bacteria that is imbedded in the plaque and is not removed.

3. The tests establishing Gleem's bacteria removal properties are "unreliable."

Before directing our comments to these three points, we would like to position Gleem as a product. Gleem is a "conventional" dentifrice, and no therapeutic claims have ever been made for Gleem in its advertising. It is our belief that the precise formula developed for Gleem (it consists of an exclusive blend of synthetic detergents covered by a patent, a unique blend of polishing agents, a binder, a humectant, and flavoring) has resulted in a distinctive product which delivers superior performance. The consumer tests we conducted before the product reached the market convinced us that the color, flavor, and texture of the product were acceptable to a broad market. The testing we conducted convinced us of the effectiveness of Gleem in removing decay- and odor-causing bacteria and combatting bacteria in the mouth. We have never claimed that Gleem prevents tooth decay. Our claims have been based simply on the fact that because of Gleem's superior detergency, it effectively removes bacteria which would lead to decay. In our advertising, all statements concerning the product's performance are presented in absolute rather than relative terms. We do not compare a Gleem brushing with a brushing using any other dentifrice. We do not compare a Gleem brushing with the use of a brush alone. We are simply stating the benefits which will result when anyone brushes his teeth with Gleem toothpaste.

Concerning the specific comments of the representatives of the ADA:

1. The statements that Gleem "is the toothpaste for people who can't brush after every meal," and that "just one brushing destroys decay- and odor-causing bacteria" are not attempts to discourage sound oral hygiene practices. As the ADA representatives pointed out, every Gleem advertisement, both in print and on television, states clearly that "brushing after every meal is best." This statement recognizes that after-meal brushing is probably desirable and is certainly not harmful. Our conclusion bearing on the desirability of after-meal brushing follows the reasoning of the American Dental Association presented at the July 17 hearing. The considerations leading to this conclusion are, however, largely theoretical since there is only one study reported in the published literature which tends to prove the value of after-meal brushing. This study, it is interesting to note, was carried out by the investigator whose qualifications to conduct clinical studies were rather seriously challenged in the testimony of Dr. Walter C. Hess at the hearings on July 17. We accept, nevertheless, the ADA's thesis that after-meal brushing is desirable even though adequate proof is lacking and have incorporated the statement that this practice "is best" in all of our Gleem advertising.

By addressing our Gleem advertising to "people who can't brush after every meal," we are simply recognizing the fact (established by our marketing investigation) that less than 10 percent of the population brush their teeth 3 times a day. By directing our advertising to the large number of people who we know do not brush their teeth three times a day, we are simply stating the positive benefit which Gleem will deliver to them.

2. The American Dental Association representatives have implied that expellable bacteria are of very little importance in the area of dental health. We do not find ourselves in agreement with this point of view. Studies conducted in our laboratories indicate that these expellable bacteria are of great importance in the decay process.

Dental plaque, the subcommittee will recall from Dr. Pearlman's testimony on the cause of decay, consists of a tenacious mass of bacteria, food residues, and cellular material adhering to the enamel surface. The plaque is described by Dr. Pearlman as "a highly active and luxuriant mass of living organisms capable of performing all the chemical reactions that such organisms usually perform." He further testified that many of the bacteria in the plaque are of a type that convert carbohydrates to acid and that is this acid which is responsible for the primary factor in the decay process.

Bacteria in the dental plaque are not necessarily permanently affixed there but are, to a very large extent, a part of the "expellable" bacteria referred to by the ADA. In support of this, we submit herewith (exhibit G) a series of colored photographs depicting the extent to which dental plaque was destroyed with a single Gleem brushing. A volunteeer subject refrained from brushing his teeth for a period of 1 week. The accumulated dental plaque was stained with a biological stain (which would attach itself to the plaque) and photographed from the front and both sides (row I). The subject then brushed his teeth with Gleem. The teeth were again stained to demonstrate the extent to which the dental plaque had been removed with the single brushing (row II). Additional studies were conducted to determine the extent to which plaque formation reoccurs at varying time intervals after brushing (rows III and IV).

Based on this study, we believe that brushing the teeth with Gleem effectively destroys the dental plaque and that the bacteria in the plaque are very much a part of the "expellable" bacteria referred to.

3. One other point of criticism was the method by which our studies on bacteria reduction were conducted. Specifically, Dr. Pearlman commented in his prepared statement that "the presence of as little as one part of GL–70 per million parts of fluid might affect the growth of the bacteria in the salt water and saliva mixture." The facts are, however, that the samples were sufficiently diluted after removal from the mouth so that even a substantial amount of dentifrice in the original mixture could not have affected bacteria growth in the culture medium. This fact may not have been available to Dr. Pearlman at the time he reviewed this study for comment.

Dr. Pearlman also criticized the technique used in that a control brushing with salt water was not made part of the testing procedure. Since no comparative claims were contemplated at the time of the testing nor have any claims of this sort ever been used, such a control would have served no useful purpose.

It is our belief that Gleem is the best conventional dentifrice that modern technology permits. Its advertising presents the benefits in a fair and straightforward manner. We do not believe that the claims made for this product in its advertising can be labeled either false or misleading.

SOME COMMENTS ON ADVERTISING

Procter & Gamble appreciates the opportunity to contribute to this review of dentifrice advertising. In addition to being anxious to contribute the foregoing technical information for the completeness of the record, we also share with the subcommittee an interest in doing whatever is necessary to keep advertising as a tool of business as useful, as believable, and as productive as possible. Procter & Gamble feels that advertising which is, in fact, "false and misleading" lessens the effectiveness of all advertising and thereby weakens one of the important forces in our economy.

Procter & Gamble has an important stake in protecting the effectiveness of advertising. For more than 75 years, advertising and other marketing skills have contributed to the success of our business and stand with research and manufacturing as our major means of serving American consumers.

Advertising is the most efficient way we know to bring the merits of a product to the attention of a mass market. It is through advertising that the benefits and economies of mass production are passed on to a broad market. Unless mass production is coupled with effective mass selling, its benefits are greatly reduced. Additionally, Procter & Gamble considers advertising to be an important educational medium. The advertising which we, and other manufacturers, have done over the years unquestionably has helped raise the standards of cleanliness, nutrition, and dental care in the United States. Specifically in regard to dental care, the annual per capital consumption of toothpaste has increased from 1.60 ounces in 1939 to 8.48 ounces in 1957. Translated into per capita brushings per week, this means that, in 1957, residents of the United States brushed their teeth an average of 3.58 times per week compared to 0.67 times per week in 1939—somewhat more than a fivefold increase. It is significant, in our opinion, that this rise in the level of dental care parallels the increase in all dentifrice advertising during this same period.

Since Procter & Gamble feels that it has a stake in the continued strength of advertising as a valuable tool of business, we have set up within our organization the mechanics for being as sure as we can be that our advertising is good advertising.

Good advertising to us means advertising that promotes the sale of a worthwhile, thoroughly pretested, useful product. Good advertising requires that the claims made for the product have support in fact. Good advertising means advertising that is in good taste and that reflects the integrity of the company offering the product for sale.

Finally, good advertising must be competently prepared and presented for the medium which is to be used. Since there is great competition for the attention of people who read magazines and newspapers or view television or listen to radio, advertising must deliver its message quickly and effectively. This requires clear, simple, and dramatic presentation of the advertising story. We are aware that there are critics of advertising who say that the simple presentation of information leads to oversimplification and that the need for dramatically effective advertising leads to overstatement. We certainly are alert to these pitfalls and conscientiously try to avoid them. We believe firmly, however, that advertising, if it is to be useful, must speak understandably and in an affirmative, even enthusiastic voice. The housewife consumer is not likely to develop enthusiasm for your product if you do not communicate that enthusiasm to her by your advertising. She is not likely to understand and believe your story if it is couched in technical language beyond her comprehension. The line between the dramatic statement and the misleading statement or between the clear statement and the oversimplified one is at times a hard one to draw. The ultimate protection for the consumer, however, lies in the fact that no advertiser can afford to promise more than the product will deliver nor can he afford to delude the consumer with false or misleading claims if he plans to stay in a profitable business or contemplates a growing market. If he plans to sell the same product to the same consumer more than once, he must have a good product and tell the truth about it.

CONCLUSION

Procter & Gamble cannot agree with the basic generalization of the American Dental Association representatives that the advertising for our dentifrice products is false, misleading, and detrimental to the public welfare. In the foregoing discussion, we have commented on the specific criticisms which the ADA has made of Crest and Gleem advertising and also have described the principles which guide the preparation of our advertising.

Quite contrary to the position of the ADA, we believe that our dentifrice advertising and the educational activities of the ADA are working toward the same goal—better dental care. We admit none of the allegations of technical inaccuracy which the ADA has made. We believe that dentifrice advertising serves the public interest by publicizing the desirability of clean teeth, and that the flavor and foaming action of the toothpaste itself makes cleaning the teeth pleasant and attractive. We are confident that more people scrub their teeth because they can use a toothpaste than would if they had only salt or soda to use on their toothbrushes.

Over the years, Procter & Gamble has worked closely with the American Dental Association and the Federal Trade Commission. On numerous occasions our people have gone to Chicago to share our research information with the ADA. In some instances, we have solicited and abided by their advice on specific dentifrice advertisements. Likewise, the ADA has given us valuable assistance in the preparation of the educational material which we make available to practicing dentists for distribution to their patients. Similarly, Procter & Gamble has established a record of full cooperation with the Federal Trade Commission and its staff in respect to any questions they might ask concerning our advertising.

We look forward to a continuation of these pleasant and helpful relationships and have every intention of cooperating with these two groups as completely as possible in the future.

EXHIBIT A

THE EFFECT OF A STANNOUS FLUORIDE-CONTAINING DENTIFRICE ON CARIES REDUCTION IN CHILDREN

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INTRODUCTION

INCREASED EFFORT is being made to resolve the problem of reducing the incidence of dental caries in children through the use of prophylactic dentifrice preparations.[1-6] While a lack of agreement exists in the reported efficiency of many of these preparations[1, 4, 7, 8] it is felt that the attention which has been focused upon the use of dentifrices may have had a beneficial effect by stimulating many persons to improve oral hygiene. It is difficult to imagine that thorough cleaning of the teeth at appropriate times would not partially alleviate dental caries incidence in children, especially in those who previously had failed to practice even moderate oral hygiene. A reduction in dental caries by the prompt brushing of the teeth with a conventional dentifrice immediately following meals has been reported.[9] Therefore, it is desirable to search for ways of improving toothbrushing habits in children, as well as providing effective dentifrices for reducing caries experience.

The incorporation of fluorides into a dentifrice as a means of increasing its value for reducing dental caries has long been considered an interesting possibility. This may be an expected consequence of previous work which clearly indicates a favorable reduction in dental caries in children using fluoridized water[10-12] or who participate in topical fluoride programs.[13-15] Furthermore, the choice of a dentifrice as the vehicle for an anticaries agent is ideal from the viewpoint of its availability to all classes of people. Milk, for example, was considered as a fluoride carrier, but this would mean the ingestion of widely different quantities of fluoride by different children. Further, there is the probability that fluorine in milk is less effective due to formation of an insoluble calcium fluoride.[2] Bread and salt have been considered but again their consumption by children is too variable to assure the ingestion of a proper amount of fluorine. Previous workers have used fluoride-containing dentifrices, but apparently with little success. A liquid and a paste dentifrice containing 500 ppm of fluorine as sodium fluoride were tested by Bibby[1] in both children and adults. No evidence of caries reduction was reported after a two-year study period. However, McClendon[3] reported a significant reduction in new cavities in adult students using a brown rock phosphate dentifrice. Shaner and Smith[2] reported that a sodium fluoride dentifrice con-

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taining 2500 ppm of fluorine as sodium fluoride used twice daily under supervision "can produce a reduction in the counts of acidogenic organisms in the saliva of humans."

It appears that if the proper dentifrice and fluoride combinations were used it might be possible to produce a significant reduction in dental caries experience in children. The nature of the abrasive seems to warrant careful consideration. Bibby[1] has stated that the fluoride dentifrice used in his study still retained its "available" fluoride. "The possibility that the mixing of sodium fluoride with other dentifrice constituents rendered it inactive is largely ruled out by preliminary test tube studies which showed that the dentifrice mixtures exerted a solubility reducing effect on powdered enamel." In light of these findings, it was considered important to select the specific fluoride and dentifrice formulation on the basis of extensive preliminary work. Stannous fluoride has been shown to be superior to sodium fluoride in reducing enamel solubility,[16-18] whole tooth solubility,[19] and caries in rats,[20-22] hamsters,[23] and human beings.[15, 24] Moreover, good evidence exists that tin fluoride is less toxic than sodium fluoride.[21, 22] The selection of a dentifrice abrasive was made on the basis of enamel solubility reduction tests on numerous abrasive-fluoride combinations. This led to the selection of heat-treated calcium phosphate as the most compatible abrasive. The remaining constituents of the tooth paste, such as binder, humectant, flavor, and detergent, were of the type sold for use in conventional tooth pastes and are commonly available. The experimental tooth paste, No. 2, contained 0.4 per cent stannous fluoride (0.1 per cent fluorine). The control tooth paste, No. 1, was the same as No. 2 in every respect except that it did not contain stannous fluoride. The two dentifrices were indistinguishable by color, flavor, consistency, or in any other way. Both were packaged in plain white containers with only the identifying numbers printed on them.*

EXPERIMENTAL METHOD

After approval of the proposed program by the dental society and school board of Bloomington, Indiana, in May, 1951, approximately 800 parents in that community were contacted in relation to the participation of their children in a dental caries program. Through the cooperation of the city school system the parents were contacted by mail and given a form letter explaining the nature of the program. From replies to this letter 514 children were selected at random to participate in the study program. Each participating child was given an initial appointment, at which time he received a thorough prophylaxis by a dental hygienist and a full mouth bite-wing radiographic examination. The child was immediately examined by a dentist with the aid of a mouth mirror and explorer. The dental caries examination was completed by charting the additional lesions observed on the radiographic films. Following the oral and x-ray examination the subject was assigned to group 1 or 2 on the basis of estimated caries expectancy.

*The composition of the dentifrice used in this study was: heat-treated orthophosphate, 42 per cent; detergent (nonsoap), 2 per cent; humectant, 25 per cent; water, 29.2 per cent; binder, 1.4 per cent; stannous fluoride, 0.4 per cent; and flavor.

Estimation of relative caries expectancy was made by multiplying a subject's DMF surfaces at the time of the initial examination by a factor corresponding to his dental age or number of permanent teeth. These factors were previously determined from another large group of grade school children[23] and represent the average ratios of expected caries to caries history at each dental age. The subject was then placed in one of nine classes based upon the level of his caries expectancy. Within this expectancy class he was assigned to group 1 or 2 so that a continuous balance was maintained. The end result of this matching procedure was that each group contained nearly the same number of subjects in each caries expectancy stratum. The average expectancy at the start of the test was 5.30 for group 1 and 5.22 for group 2. If only those subjects who completed the study are considered, then the average expectancy was 5.26 for group 1 and 5.29 for group 2. The corresponding average number of DMF teeth at the first examination for those who completed the study was 7.85 for group 1 and 7.63 for group 2.

After the child was assigned to one of the groups, he was given a supply of the corresponding dentifrice and a new toothbrush. The entire family of each subject was also supplied with the same dentifrice to minimize the possibility that subjects might use another dentifrice which would otherwise have been available. Six weeks later the patient returned for an oral hygiene evaluation. At this time the parents were asked if they had any complaints or suggestions relative to the program and the child's mouth was examined for irritation, stain, general oral hygiene, and other factors that might represent the nature of the oral hygiene being practiced. The parents were questioned concerning the child's brushing habits, with emphasis on frequency and time of day, and about their likes and dislikes of the dentifrice they were receiving. At this visit, the child was asked to brush his teeth in the same manner as performed at home. The time required to do this and the method of toothbrushing were recorded by a hygienist standing in such a location that the child did not know of her presence. Following this, the child was given another appointment to return six months from his initial visit. At this time the hygienist again performed a thorough prophylaxis, bite-wing x-rays were again made, and the clinical dental caries data recorded by the same dentist. The order in which the children reported for examination was in no way related to the type of dentifrice being used. Precautions were taken to prevent the examining dentist from knowing or guessing which dentifrice a child was using. The dentist examined a child only after a thorough prophylaxis so that telltale signs of treatment, if any, were removed. The examination card upon which the dental findings were recorded was completely masked except for the blank spaces to be filled in. This procedure was adopted to minimize the possibility for bias in the examination, to make the initial and subsequent examinations completely independent of each other, and to equally distribute between the two groups the effect of unavoidable changes in standards of judgment which occur from day to day or over longer periods.

RESULTS AND DISCUSSION

Table I shows the caries experience for each group expressed in terms of several indices on the basis of average increase in caries units per person. This expression is used rather than proportion of total teeth attacked because the groups were balanced on the basis of caries expectancies of the individuals. Table I shows a 53 per cent reduction in DMF teeth for the group using the stannous fluoride dentifrice when compared to the control group. When the DMF surfaces index is used the reduction for the stannous fluoride dentifrice group is 72 per cent. Both of these reductions are highly significant as indicated by the low probabilities. It is interesting that the results by the two indices DMFT and DMFS are somewhat different. This could be explained in two ways: (1) the DMF surface index is more sensitive to the degree of severity of caries attack per tooth; and (2) the DMF tooth index as ordinarily used counts only new decay in previously caries free teeth, while the DMF surface index counts new decay in previously caries-free surfaces of all teeth. This latter point is thought to be the main reason for the difference. If the DMF tooth index is used to apply only to those teeth which are excluded by the conventional methods of computation, the percentage reduction in the No. 2 group is 100 per cent. This method of using the DMF tooth index takes into account 52 per cent of the teeth which developed new caries during the test. The conventional use of the DMF tooth index takes into account the other 48 per cent of the teeth which developed new caries. A rough average of the percentage reductions by the two methods would give a reduction in total DMF teeth of 77 per cent or about the same as the reduction by total DMF surfaces.

The last three columns in the first part of Table I show the caries increments by DMF surfaces divided into three components: proximal surfaces,

TABLE I

AVERAGE INCREASE IN CARIES FOR SIX-MONTH PERIOD

	DMF TEETH	TOTAL DMF SURFACES	DMF PROXIMAL SURFACES	DMF OCCLUSAL SURFACES	DMF BUCCAL LINGUAL SURFACES
Group 1 (Control) n = 197	0.701	1.812	0.701	0.574	0.536
Group 2 (SnF_2) n = 223	0.327	0.516	−0.072*	0.426	0.161
% Reduction	53.35	71.52	100.0	25.78	70.07
t Value	3.00	5.53	5.94	1.24	3.13
Probability	.003	<.00001	<.00001	0.22	.003

Analysis of Variance for Surface Types

SOURCE	MEAN SQUARE	D.F.	F VALUE	PROBABILITY
Dentifrices	58.61	1	36.86	<.01
Surfaces	4.82	2	3.03	.05
D-S Interaction	10.44	2	6.57	<.02
Error	1.59	1254		

*Although this figure indicates a decrease in caries, it is recognized that carious lesions may undergo arrestment but not repair. For computation of per cent reduction this figure was taken as zero.

occlusal surfaces, and buccal and lingual surfaces. It is apparent that the stannous fluoride dentifrice protected the different surfaces in widely different degrees. This phenomenon is called dentifrice-surface (D-S) interaction. The Analysis of Variance in Table I is computed for different surface types, and for both dentifrices and supplies several items of information. The high F value for dentifrices indicates that the three surface types taken together show a highly significant reduction in caries for the No. 2 group. The difference in caries rates for the three surface types is significant at the 0.05 level even though all the surfaces in the No. 1 group show about the same rate of caries attack. The F value for D-S interaction indicates that the difference in protection which the three surface types exhibit is significant with a probability near the 0.01 level.

The most marked protection against caries occurred on the proximal surfaces of the teeth in children using the stannous fluoride tooth paste. The 100 per cent reduction figure which is very highly significant indicates the possibility of complete protection for proximal surfaces. Occlusal surfaces showed the lowest degree of protection. They were the only surfaces in which the difference between control and experimental groups was not significant. The buccal and lingual surfaces showed about the same degree of protection as the average for all the surfaces.

Table II shows the number of subjects, average caries increments and the percentage reduction in caries within the different age groups. Two interesting aspects of these data should be noted: (1) the consistency with which the stannous fluoride tooth paste appears to have protected all age groups and (2) the definite trend toward increased protection with increasing age. This trend was tested for significance by a specific test[26] for that purpose. The probability of getting a sequence that is farther removed from an expected sequence where there is no real trend is only 0.002. Both groups have an unusually high proportion of 7- and 8-year-old children for a grade school sample. However, it is felt that the only effect of this disproportion would be to bias the results on the conservative side since the caries reductions for these ages are almost the lowest in the group.

TABLE II

CARIES INCREMENTS AS AVERAGE DMF SURFACES BY AGE

AGE YR.	GROUP 1 CONTROL		GROUP 2 SnF_2		REDUCTION %
	N	MEAN	N	MEAN	
6	14	2.07	16	1.56	24.6
7	39	1.77	38	0.76	57.1
8	42	1.00	42	0.81	19.0
9	18	1.28	21	0.33	74.2
10	12	1.67	21	0.14	91.6
11	15	2.87	14	1.21	57.8
12	11	1.73	20	0.40	76.9
13	12	2.67	21	0.29	89.1
14	21	2.48	13	0.23	90.7
15 and 16	13	2.15	17	0.06	97.2

In view of the reported failure of a sodium fluoride dentifrice to reduce dental caries[1] a positive result with a stannous fluoride dentifrice might be expected only if the compatibility of the fluoride and the dentifrice were improved. On the other hand, several factors may have contributed to the marked reduction of caries in such a short period of time. Tin in combination with fluoride is superior to the sodium salt for topical applications.[13, 14] The daily application of stannous fluoride to the teeth may enhance its effectiveness. Topical studies with sodium fluoride indicate that a prophylaxis prior to treatment increases the effect. The stannous fluoride tooth paste had its most marked effect upon the proximal surfaces which are generally considered the most difficult surfaces to clean by brushing. This may indicate that stannous fluoride is retained by the plaque or debris in the interproximal area and its effect thereby enhanced. If this is true, any anticaries agent may be more effective on the proximal surfaces, because those areas which act as food repositories may serve the same purpose for an anticaries agent.

Some considerations relative to possible toxicity of such a product are necessary before any unrestricted recommendation by the profession can be made, even in the light of such pronounced anticaries effect as demonstrated by these data. The experimental dentifrice used contained 1,000 micrograms of fluorine and 3,200 micrograms of tin per gram of dentifrice and each tube contained a total of 150 mg. of fluorine. If a child brushed his teeth with 1 gram of the fluoride tooth paste and swallowed the entire amount he would ingest 1 mg. of fluorine. Although it is improbable that any child or adult would swallow all of the dentifrice, such a circumstance would provide only approximately the amount of fluoride as contained in one liter of communal water at a fluorine concentration of 1 ppm. People living in areas where the water is naturally fluoridated above the optimum level frequently ingest several times that amount of fluorine daily for their entire lives with no serious effect.

SUMMARY

A stannous fluoride-containing dentifrice at a fluorine concentration of 1,000 ppm and a tin concentration of 3,200 ppm results in a pronounced reduction in dental caries in 6- to 15-year-old children after using the dentifrice in an unsupervised manner for a period of six months. When compared to an identical control dentifrice not containing stannous fluoride, a 53 per cent reduction in DMF teeth and a 72 per cent reduction in DMF surfaces resulted. There appeared to be complete protection against interproximal lesions, while the reduction in buccal-lingual surfaces was 70 per cent and occlusal surfaces 26 per cent. All of the reductions are highly significant except the reduction in occlusal surfaces. The reduction of caries appears to be related to the subjects' ages, with the greatest protection occurring in the older age groups of the children. The effect of possible toxic effects through the continued use of a stannous fluoride dentifrice is discussed.

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EXHIBIT B

Effect of a stannous fluoride-containing dentifrice on caries reduction in children II. Caries experience after one year

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The idea of using a lower level of fluoride than commonly employed in the technic of topical applications but applying it more frequently to increase partially resistance to dental caries is not new. In commenting on this subject Bibby[1] stated:

> It seems obvious that if infrequent treatment can cause such definite changes in the progress of caries, more frequent treatments, the use of improved techniques of application or treatment using a more active fluorine reagent might accomplish a great deal more in the control of dental decay.

In this respect the use of a fluoride dentifrice might be ideal, since it would combine frequent applications with maximum convenience, because the fluorine would be applied as part of a regular oral hygiene procedure.

The data obtained on a stannous fluoride dentifrice reported in this study are the result of several years of intensive effort to find a highly active anticaries compound and a means of keeping it effective when incorporated in a dentifrice. The first report[2] indicated that after six months of unsupervised use of a paste dentifrice containing stannous fluoride, the dental caries rate in children was reduced 53 per cent in DMF teeth and 71 per cent in total DMF surfaces. Since one of the important considerations of the utility of such a dentifrice is its continued effectiveness, this report presents the findings at the end of one year.

EXPERIMENTAL PROCEDURE

The method of conducting the study has been reported in detail.[2] Five hundred and fourteen children were divided in two groups according to an estimate of their "caries expectancy." The two groups of children were provided with dentifrices which were identical except that one contained 4,000 ppm stannous fluoride. This means that approximately 1.0 mg. fluorine and 3.0 mg. tin as stannous fluoride were used per gram of dentifrice. The composition of the dentifrice was as follows: heat-treated calcium

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Table 1 • Average increase in caries experience for one-year period

	Children	DMFS in previously caries-free teeth	DMFS in previously DF teeth	DMFS in teeth erupting during test	New proximal surfaces decayed	New occlusal surfaces decayed	New buccal and lingual surfaces decayed	Total new DMFS	New DMFT
Group 1*	209	1.45	1.27	0.30	1.29	1.09	0.63	3.01	1.31
Group 2†	214	0.86	0.48	0.19	0.21	0.77	0.55	1.55	0.65
Percentage decrement in caries rate		40.5	62.1	37.9	83.7	29.8	12.8	49.3	50.6
Probability		<.001	<.005	<.014	<.00001	<.014	>.05	<.0001	<.00001

*Control group
†Stannous fluoride group

orthophosphate, 42 per cent; detergent (nonsoap), 2 per cent; humectant, 25 per cent; water, 29.2 per cent; binder, 1.4 per cent; stannous fluoride, 0.4 per cent and flavor. The children composing Group 1 received the nonfluoride dentifrice, whereas the children in Group 2 received the stannous fluoride dentifrice. The use of the dentifrice was not supervised. The children, ranging in age from 5 to 15 years, returned to the dental clinic at six month intervals in order to receive a dental prophylaxis, complete bitewing roentgenographic examinations and clinical dental caries examination.

DATA AND DISCUSSION

After one year of participation in the experimental dental caries program, 423 children returned for re-examination. Table 1 shows the average dental caries increments in terms of new DMF teeth and total new DMF surfaces along with various components of DMF surfaces in the two groups of children. Use of the stannous fluoride dentifrice resulted in a decrement in caries rate of 50.6 per cent in teeth which were noncarious at the time of the initial examination and a 49.3 per cent decrement in caries rate in all new DMF surfaces. The decrement in terms of total DMF surfaces is highly significant with a probability less than 0.0001. These estimates of effectiveness obtained at the end of the first year are somewhat lower than those obtained after six months.

The effect of the stannous fluoride-containing dentifrice on previously carious teeth is of special interest. There was a decrement of 40.5 per cent at the end of one year in DMF surfaces in previously caries-free teeth, whereas a 62.1 per cent decrement was observed in the surfaces of teeth that were previously carious. The finding of greater effectiveness in previously carious teeth is similar to the observation with an aqueous solution of stannous fluoride applied topically to children's teeth.[3] In the study on topical applications, stannous fluoride resulted in a 97 per cent decrement in DMF surfaces in previously carious teeth and 52 per cent in DMF surfaces in previously caries-free teeth. When sodium fluoride was applied, the opposite effect occurred, that is, a lower degree of effectiveness was observed in previously carious teeth (28 per cent decrement) than in previously caries-free teeth (38 per cent decrement). This characteristic of topical sodium fluoride

3. Howell, C. L., and others. Effect of topically applied stannous fluoride on dental caries experience in children. J.A.D.A. 50:14 Jan. 1955.

treatment seems well established by several previous reports by independent workers.[4-8] Thus it appears that stannous fluoride was most effective in those situations where topically applied sodium fluoride appears to be less effective.

Columns 6, 7 and 8 in Table 1 show the caries increments by DMF surfaces divided into their various surface components: proximal, occlusal, buccal and lingual. The most pronounced effect was in the proximal surfaces, which showed an 83.7 per cent decrement. This decrease compares favorably with the 100 per cent decrement at the end of 6 months, or a difference in the estimate of effectiveness of only about 15 per cent. The decrement found at the end of one year in the occlusal surfaces is similar to that found at the end of six months, there being a 29.8 per cent decrement after one year and 25.8 per cent at six months. The greatest difference, as observed in the protection afforded the various surfaces by the stannous fluoride dentifrice, can be noted in a comparison between the six month and one year data in the buccal and lingual surfaces. After six months there was reported a 70.1 per cent reduction in caries rate in the buccal and lingual surfaces, while after a full year the children in Group 1 had only a 12.8 per cent decrement as compared with those in Group 2. An explanation for this is lacking at the present time.

That the stannous fluoride dentifrice was effective in reducing the initiation of new dental caries in teeth erupting during the one year study period is indicated by the data in Table 1, which shows that the children's teeth had a 37.9 per cent decrement in surfaces attacked in the stannous fluoride group. The fact that this figure is somewhat lower than the over-all decrement in DMF surfaces of 49.3 per cent may reflect the order in which the different tooth surfaces are attacked by caries. The occlusal surfaces of the most susceptible teeth are usually the first to decay, and it is these surfaces which showed a low decrement in this study.

Table 2 • Average increase in caries experience in DMF surfaces by age

Age in years	Group 1 Control		Group 2 SnF_2		Percentage decrement
	Number	Average	Number	Average	
6	18	2.33	17	1.65	29.2
7	45	2.11	42	1.09	48.3
8	44	1.45	43	1.87	5.5
9	18	2.56	22	0.73	71.5
10	10	1.50	19	1.11	26.0
11	16	5.31	14	1.93	63.7
12	11	4.45	16	1.81	59.3
13	15	5.27	15	2.73	48.1
14	20	5.20	13	1.77	66.0
15	12	4.25	13	2.85	33.0

Among the children in Group 1 there were a total of 66 reversals in diagnosis, whereas there were 178 in the children in Group 2. Again, this finding is reminiscent of the study of topical applications of sodium fluoride and stannous fluoride[8] in which there was a significantly greater number of reversals in diagnosis in the children treated with stannous fluoride than in either the control or sodium fluoride groups. It has been reported[9] that reversals in diagnosis are to be expected in any clinical dental caries study conducted in such a manner

4. Knutson, J. W., and Armstrong, W. D. Effect of topically applied sodium fluoride on dental caries experience. Pub. Health Rep. 58:1701 Nov. 19, 1943.

5. Knutson, J. W., and Armstrong, W. D. Effect of topically applied sodium fluoride on dental caries experience; report of findings for second study year. Pub. Health Rep. 60:1085 Sept. 14, 1945.

6. Knutson, J. W., and Armstrong, W. D. Effect of topically applied sodium fluoride on dental caries experience; report of findings for third study year. Pub. Health Rep. 61:1683 Nov. 22, 1946.

7. Knutson, J. W., Armstrong, W. D., and Feldman, F. M. Effect of topically applied sodium fluoride on dental caries experience; report of findings with two, four and six applications. Pub. Health Rep. 62:425 March 21, 1947.

8. Galagan, D. J., and Knutson, J. W. Effect of topically applied sodium fluoride on dental caries experience; experiments with sodium fluoride and calcium chloride; widely spaced applications; use of different solution concentrations. Pub. Health Rep. 63:1215 Sept. 17, 1948.

9. Radike, A. W., and Muhler, J. C. Effect of reversals in diagnosis on the interpretation of clinical dental caries tests. (Abst.) J. D. Res. 33:682 Oct. 1954.

that the initial and second examinations are completely independent of each other as they were in both of the studies in which stannous fluoride was used. It has been suggested[9] that where the experimental group has a greater proportion of reversals than the control group, this difference may be due in part to the arrest of incipient carious lesions.

Table 2 shows the number of subjects in each age group and the percentage decrement in caries rate at each age. There is no indication in these data of a relationship between age and the effect of the stannous fluoride dentifrice. Such a relationship was apparent in the data at the end of six months.[2]

SUMMARY

After 12 months of unsupervised use of a stannous fluoride dentifrice, a decrement of 51 per cent in DMF teeth and 49 per cent in total DMF surfaces was noted. The proximal surfaces were best protected from caries, showing an 84 per cent decrement, while the occlusal surfaces had a decrement of 30 per cent. The stannous fluoride dentifrice appeared to affect the teeth already decayed to a greater degree than previously carious-free teeth. The age of the subject apparently was not a major influence on the effectiveness of the stannous fluoride dentifrice.

EXHIBIT C

A comparison between the anticariogenic effects of dentifrices containing stannous fluoride and sodium fluoride

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It is well established that sodium fluoride added to a fluorine-deficient water supply or applied topically to the erupted teeth of children will reduce the incidence of dental caries.[1,2] In an attempt to find fluoride compounds with greater anticariogenicity than sodium fluoride, a considerable amount of experimental work has been undertaken. Numerous studies involving a variety of different experimental technics have all indicated the superiority of the tin fluorides over sodium fluoride. These include solubility reduction tests on powdered dental enamel[3] and intact enamel surfaces,[4] experimental dental caries studies in rats[5-7] and hamsters,[8] as well as human clinical topical studies.[9,10] In addition, it has been reported recently that with both children[11] and adults,[12] stannous fluoride is effective in reducing the incidence of dental caries when placed in a dentifrice in which the abrasive is a heat-treated calcium phosphate.

It thus became of interest to determine whether the use of a dentifrice containing sodium fluoride and one containing stannous fluoride would result in similar reductions in dental caries in children. This report indicates the effect of each of these fluorides when placed in identical dentifrices. The results after one year corroborate the superiority of stannous fluoride as an anticariogenic agent.

This work supported by a grant from the Procter and Gamble Company, Cincinnati.

*School of Dentistry and department of chemistry, Indiana University.

†Procter & Gamble Company.

1. Hutton, W. L.; Linscott, B. W., and Williams, D. B. Brantford, Ontario, fluoridation study. J.A.D.A. 49:183 Aug. 1954.

2. Knutson, J. W., and Armstrong, W. D. Effect of topically applied sodium fluoride on dental caries experience. Public Health Rep. 58:1701 Nov. 19, 1943.

3. Muhler, J. C., and Day, H. G. Relation of pH to the effectiveness of sodium fluoride and stannous fluoride in decreasing enamel solubility. J.D. Res. 31:102 Feb. 1952.

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5. Muhler, J. C., and Day, H. G. Effect of stannous fluoride in food and in drinking water on caries prevention in rats on high sucrose and coarse corn diet. J. Nutrition 44:413 July 1951.

6. Muhler, J. C.; Nebergall, W. H., and Day, H. G. Preparations of stannous fluoride compared with sodium fluoride for the prevention of dental caries in the rat. J.A.D.A. 46:290 March 1953.

7. Muhler, J. C.; Nebergall, W. H., and Day, H. G. Studies on stannous fluoride and other fluorides in relation to the solubility of enamel in acid and the prevention of experimental dental caries. J.D. Res. 33:33 Feb. 1954.

8. Radike, A. W., and Muhler, J. C. Incidence of dental caries in hamsters receiving two different water soluble fluorides at low concentration. J.D. Res. 32:807 Dec. 1953.

9. Howell, C. L., and Muhler, J. C. Effect of topically applied stannous chlorofluoride on dental caries experience in children. Science 120:316 Aug. 20, 1954.

10. Howell, C. L., and others. Effect of topically applied stannous fluoride on the dental caries experience in children. J.A.D.A. 50:14 Jan. 1955.

11. Muhler, J. C., and others. Effect of a stannous fluoride-containing dentifrice on caries reduction in children. J.D. Res. 33:606 Oct. 1954.

12. Muhler, J. C., and others. Effect of a stannous fluoride-containing dentifrice on dental caries in adults. J.D. Res. In press.

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EXPERIMENTAL STUDY

Eight hundred and fifty-four grade school children were divided into three groups as follows: After the initial oral and roentgenographic examination of a subject, his total previous caries experience in terms of DMF surfaces in permanent teeth was corrected by a factor corresponding to his dental age. This factor is one of a series of ratios relating past to subsequent DMF surfaces. These ratios were previously determined using data from 2,000 grade-school children. The corrected term was taken as an indication of caries expectancy, and the subject assigned to one of nine classes on this basis. Within each class he was assigned to one of the three treatment groups at random.

The dental clinic, where the work was conducted, is located on the campus of Indiana University. Children reported to the clinic from all parts of the Bloomington, Ind., area in mixed order each day. The examiner had no information about any child relative to group assignment, previous examination data, and so on. These and additional precautions were taken to minimize bias which could occur as the result of association between treatment groups and schools, economic levels, racial types, time of year, or examiner knowledge. The three groups of children, aged 5 to 15 years, were provided with a dentifrice differing only in regard to added fluoride (Table 1). The stannous fluoride-containing dentifrice contained 1,000 ppm fluorine as stannous fluoride, the sodium fluoride dentifrice contained 1,000 ppm fluorine as sodium fluoride, and the control dentifrice contained no added fluoride of any kind.

The entire family of each child was supplied with the dentifrice assigned to the child. Although this increased the cost of the study considerably, it provided additional assurance that the child would use only the dentifrice assigned.

Table 1 • Composition of dentifrices used in study (in grams per cent)

Ingredients	Control	Stannous fluoride	Sodium fluoride
Heat-treated calcium orthophosphate	42	42	42
Detergent (non-soap)	2	2	2
Humectant	25	25	25
Water	29.6	29.2	29.38
Binder	1.4	1.4	1.4
Stannous fluoride	—	0.4	—
Sodium fluoride	—	—	0.22
Flavor, q.s.	—	—	—

No instructions were given to any of the children for brushing the teeth so that each child could be expected to practice his usual toothbrushing methods.

All of the children from whom data are reported in this study were given a thorough dental prophylaxis, and complete bitewing roentgenograms were taken at the initial visit to the dental clinic. One to three days later the child returned to the clinic to receive a careful clinical dental caries examination with the aid of the roentgenograms, good light, compressed air, sharp explorers and mouth mirror. This entire procedure was repeated after 6 and after 12 months.

The criteria for diagnosis of dental caries were carefully standardized. Repeated examinations were made after six weeks on 50 subjects and showed an error of only 7 per cent in reproducibility. All dental examinations were made by one examiner.

DATA AND DISCUSSION

Table 2 shows the number of subjects available at each examination period for each treatment group and age. The loss from all three groups at the end of six months amounted to 15 per cent and at the end of one year, 23 per cent. These losses were distributed rather evenly among the three groups. Table 3 shows the average caries experience at the beginning of the test for each group. If

Table 2 • Distribution of subjects by age and group at each examination

Age at start of test	Number of subjects available at start of test			Number of subjects available after 6 months			Number of subjects available after 12 months		
	Control	Sodium fluoride	Stannous fluoride	Control	Sodium fluoride	Stannous fluoride	Control	Sodium fluoride	Stannous fluoride
6	14	12	14	11	9	9	11	9	8
7	48	51	39	41	40	30	39	40	29
8	37	40	36	31	35	29	32	32	27
9	28	38	44	27	32	40	27	29	32
10	34	21	31	29	18	30	22	15	30
11	26	34	34	24	30	29	21	26	27
12	31	28	24	28	21	21	25	19	17
13	19	25	27	18	18	25	17	17	20
14	21	19	26	16	17	23	16	14	19
15–16	20	16	15	19	13	12	12	11	10
All ages	278	284	290	244	233	248	225	212	219

Table 3 • Average DMF surfaces in permanent teeth at time of initial examination

Age at start of test	DMFS at the initial exam. for subjects who entered test			DMFS at the initial exam. for subjects who completed 6 mos.			DMFS at the initial exam. for subjects who completed 12 mos.		
	Control	Sodium fluoride	Stannous fluoride	Control	Sodium fluoride	Stannous fluoride	Control	Sodium fluoride	Stannous fluoride
6	2.2	1.8	2.4	2.1	1.6	2.4	2.1	1.6	2.6
7	3.6	3.2	3.7	3.6	3.4	3.6	3.7	3.4	3.9
8	4.9	5.4	4.9	4.4	5.3	4.7	4.4	5.4	4.8
9	7.4	7.9	6.7	7.4	7.7	6.7	7.4	7.3	6.0
10	7.3	7.5	8.2	7.6	7.6	8.0	7.2	7.5	8.0
11	12.6	9.4	10.4	12.1	8.1	10.7	10.8	8.4	10.8
12	18.0	16.8	13.6	17.7	19.1	13.2	18.4	18.2	11.7
13	13.9	16.2	17.0	13.7	15.4	17.0	13.6	15.2	15.0
14	13.6	19.1	15.8	13.4	20.3	16.3	13.4	21.0	15.7
15–16	24.4	24.0	23.9	24.0	26.5	21.5	20.5	27.9	23.5
All ages	10.0	10.0	9.7	10.0	10.2	9.7	9.1	10.0	9.5

Table 4 • Dental caries increments during the one-year test period

	After 6 months			After 12 months		
	Control	Sodium fluoride	Stannous fluoride	Control	Sodium fluoride	Stannous fluoride
DMF teeth increment	0.700	0.644	0.382	1.268	1.240	0.838
% reduction in caries rate	——	8.0	45.4	——	2.2	33.9
Probability	——	>0.5	<0.025	——	>0.50	<0.03
DMF surfaces increment	1.177	1.009	0.651	2.424	2.184	1.552
% reduction in caries rate	——	14.3	44.7	——	9.9	36.0
Probability	——	>0.40	<0.025	——	>0.40	<0.013

these figures are taken as an indication of balance between groups, some variation may be noted at the 6 and 12 month examinations due to the loss of subjects from the test program. Although the effect of this loss on balance does not appear to be pronounced, it is a problem that deserves further study.

Table 4 shows the average dental caries increments in terms of DMF teeth and total new DMF surfaces at the end of 6 months and 12 months in the three groups of children. The sodium fluoride data indicate only small reductions in the dental caries rate after 6 and 12 months. Although the small differences were consistently positive they are not statistically significant. On the other hand, in the children receiving the dentifrice containing stannous fluoride, there was a 45 per cent reduction in caries rates after 6 months and 36 per cent after 12 months. In both instances these reductions are significant. The differences between the 6 and 12 month reductions are not significant.

These data support results in other reports that were based on the use of a stannous fluoride-containing dentifrice.[13] These reports indicated that there was a reduction of 51 per cent in DMF teeth and 49 per cent in DMF surfaces as compared with controls who used a similar dentifrice not containing fluorine. Similarly, when an identical dentifrice was used by college students for a one year period, there was a 55 per cent reduction in DMF teeth and 50 per cent in DMF surfaces.[12]

Since topically applied stannous fluoride[10] and stannous chlorofluoride[9] appear to be superior to topically applied sodium fluoride in reducing the dental caries experience in children, these latter data strengthen the evidence that tin fluorides are superior to sodium fluoride in their anticariogenic action.

If additional results continue to support these observations, they will give impetus to the idea that even more effective anticariogenic agents may be found. Since topical treatments, in which class dentifrices may be listed, serve as an adjunct to communal fluoridation, proper nutrition, adequate dental attention, proper toothbrushing habits and the like, these studies give promise of expanding the benefit of fluorides to an even larger number of people.

SUMMARY

A clinical dental caries test has been conducted for a period of one year for the purpose of comparing the anticariogenic effects of sodium fluoride and stannous fluoride in a paste-type dentifrice when used by grade school children in accordance with their usual toothbrushing habits.

The stannous fluoride-containing dentifrice caused a significant reduction in dental caries while the sodium fluoride-containing dentifrice had no significant effect.

ADDENDUM

After this report was submitted for publication, additional data were published[14] showing that a sodium fluoride dentifrice had no significant effect in reducing the rate of tooth decay among children. In the Shaw publication, reference is made to an unpublished report by W. D. Wellock and B. G. Bibby regarding a large scale clinical test which showed a zero reduction in dental caries rate among children using a calcium phosphate dentifrice containing 0.1 per cent sodium fluoride.

13. Muhler, J. C., and others. Effect of a stannous fluoride-containing dentifrice on caries reduction in children. II. Caries experience after one year. J.A.D.A. 50:163 Feb. 1955.

14. Shaw, J. H. Fluoridation as a public health measure. Washington, D. C., American Association for the Advancement of Science, 1954. p. 158-159.

EXHIBIT D

THE EFFECT OF A STANNOUS FLUORIDE-CONTAINING DENTIFRICE ON DENTAL CARIES IN ADULTS

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NUMEROUS publications concerning dental caries control measures indicate that the primary emphasis has been placed upon the reduction of caries rates in children. This is rightly so because the period of greatest dental caries activity is usually during the early years following the eruption of the permanent dentition. However, this high caries rate during childhood and adolescence is a factor which helps decrease caries incidence in adults by lowering the number of susceptible tooth areas available for decay. It is obvious that measures which decrease the dental caries incidence in children will result in a more complete natural dentition in adults, but it would be unfortunate if the teeth saved by effective caries control in childhood were lost in the early adult years by increased caries activity. Successful caries control methods which are primarily effective in children will enlarge the need for a successful method of reducing caries activity in adults. Even without this enlarged need, the current incidence of dental caries in adults calls for an increased effort toward a solution of this problem.

Previous attempts to use prophylactive agents to reduce the dental caries experience in the adult population have been reported, and varying degrees of success have been indicated. Arnold, Dean, and Singleton[1] studied the effect of the single application of a 1 per cent sodium fluoride solution, at pH approximately 4.5, on 94 Coast Guard cadets with a mean age of approximately 20 years. At the end of one year, re-examination did not indicate a reduction in caries rate for the fluoride-treated group.

Klinkenberg and Bibby[2] treated 139 dental students, aged 18 to 40 years, with a 1 per cent sodium fluoride solution. The fluoride was applied topically by single treatments at intervals of 3 months, throughout a period of approximately 14 months, after which time the subjects were re-examined. The quadrants treated with sodium fluoride showed 56.6 per cent less new DMF surfaces than did the untreated control teeth of the opposite sides of the mouth. Rickles and Becks[3] report a 36.8 per cent reduction in DMF surfaces and an 18.7 per cent reduction in DMF teeth when 4 applications of a 2 per cent sodium fluoride solution was applied topically to the teeth of 25 adults, 22 to 34 years of age. Kutler and Ireland[4] reported that there was no significant

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reduction in the dental caries incidence on the basis of total new caries when 147 medical students, 20 to 24 years of age, received 4 half-mouth applications of a 2 per cent sodium fluoride solution. Bibby[5] tested a dentifrice containing 500 μg F per gram (as sodium fluoride) and found no evidence of a reduction of caries activity in a group of college students who used the dentifrice during a two-year study period. Similarly, Bibby, Zander, McKelleget, and Labunsky[6] reported that a mouthwash containing 500 μg F per milliliter (as sodium fluoride) used 3 times weekly for 1 year did not reduce caries activity in 31 dental students below that of 15 students who used a control fluoride-free mouthwash. McClendon and Foster,[7] however, stated that in a one-year test there were less new caries in the teeth of medical students brushing their teeth with powdered rock phosphate than in controls not using rock phosphate as a dentifrice.

Many of these studies were conducted on small groups and may be of doubtful significance. Therefore, it was of interest to study larger groups and of special interest to consider the effect of a dentifrice containing stannous fluoride. Previous work has indicated a favorable effect in children[8, 9] who have used a similar dentifrice, as well as a pronounced reduction in caries experience in children when stannous fluoride was topically applied.[10]

EXPERIMENTAL PROCEDURE

The method of conducting this study was identical to that previously reported for a group of grade school children using a similar dentifrice,[8, 9] except that a slightly different procedure was used for the assignment of subjects to treatment groups. Students from the freshman class at Indiana University, ranging in age from 17 to 36 years, were given a dental prophylaxis followed by a thorough clinical examination with the aid of complete bite-wing radiographs. The subjects were divided into 9 classes on the basis of previous caries experience. Within each class they were assigned to either Group I or Group II by a randomizing procedure which maintained almost equal numbers of subjects in each group. The total DMFS at the start of the study for those who completed the test year was 27.7 for Group I and 26.9 for Group II. By this criterion a good balance is indicated.

The 2 groups were provided with dentifrices the composition of which were identical except that one contained 4 mg. of SnF_2, or approximately 1 mg. F and 3 mg. Sn per gram of dentifrice. The adults comprising Group I received the nonfluoride dentifrice, while those in Group II received the dentifrice containing stannous fluoride. The students returned at six-month intervals to receive a dental prophylaxis, complete bite-wing radiographic examination, and clinical dental caries evaluation.

After the first 6 weeks, the patients were asked how frequently and at what times during the day they brushed their teeth. Following this they were given a new toothbrush and asked to brush their teeth exactly as they would do at home. These results were used in part to correlate the effectiveness of the dentifrice in those adults with good oral hygiene as opposed to those with a poor state of oral hygiene, as well as to compare the frequency of brushing and other oral health habits in this adult group with a similar study in children.[11]

DATA AND DISCUSSION

The effect of the stannous fluoride dentifrice is shown in Table I. The best estimate of the effect of the stannous fluoride dentifrice is given at the right of Table I as total new decayed, missing, and filled surfaces (total new DMFS). In terms of this index the college students who used the stannous fluoride dentifrice experienced a 50.4 per cent reduction in dental caries rate during the first six-month period and a 41.6 per cent reduction at the end of the first year when compared to the control group. Both of these reductions are significant with probabilities less than 0.01 and 0.016. The 2 percentage figures, while somewhat different, cannot be considered in disagreement for a study of this size.

TABLE I

AVERAGE INCREASE IN DENTAL CARIES EXPERIENCE IN INDIANA UNIVERSITY STUDENTS USING A STANNOUS FLUORIDE AND CONTROL DENTRIFRICE FOR A ONE-YEAR PERIOD

		CARIES INCREMENTS IN TERMS OF SEVEN INDICES						
		NEW DMFS IN PREVIOUSLY CARIES-FREE TEETH	NEW DMFS IN PREVIOUSLY CARIOUS TEETH	NEW DMFS PROXIMAL SURFACES	NEW DMFS OCCLUSAL SURFACES	NEW DMFS BUCCAL AND LINGUAL SURFACES	TOTAL	
							NEW DMFT	NEW DMFS
6-month period	Group I. 180 Subjects Control Dentifrice	0.656	0.694	0.839	0.317	0.194	0.311	1.350
	Group II. 179 Subjects SnF_2 Dentifrice	0.497	0.173	0.369	0.196	0.106	0.140	0.670
12-month period	Group I. 157 Subjects Control Dentifrice	0.860	1.153	1.229	0.478	0.306	0.393	2.013
	Group II. 165 Subjects SnF_2 Dentifrice	0.727	0.448	0.667	0.297	0.212	0.182	1.176
% Reduction in caries rate	6-month	24.2	75.1	56.0	38.2	45.4	55.0	50.4
	12-month	15.5	61.1	45.7	37.9	30.7	53.7	41.6

It is recognized that the number of subjects, although larger than in many previous adult studies, is not large enough to provide an estimate of effectiveness having a high degree of precision. However, two points of interpretation are justifiable: at the end of 6 months a pronounced effect was observed in those students using the stannous fluoride dentifrice, and the effect remained after 1 year.

The components of the total DMF surfaces index show marked variability as has been observed in the previous 2 reports concerned with the effect of the dentifrice on children.[8, 9] For example, at the end of 6 months the interproximal surfaces showed the greatest benefit with a reduction of 56 per cent, while the occlusal surfaces showed the least benefit with a reduction of 38.2 per cent. The indication of lowest effectiveness is found in the new DMF surfaces in previously caries-free teeth, while the greatest effectiveness is in the new DMF surfaces in previously carious teeth. This latter observation was similarly made

in previous studies in which a stannous fluoride dentifrice was used,[8, 9] as well as in a topical stannous fluoride study.[10] These data clearly illustrate the danger of introducing large errors by attempting to represent the over-all result of a test by reporting only one part of the newly decayed surfaces rather than the total new DMF surfaces.

Since it has been determined[5] that a sodium fluoride–containing dentifrice is without effect in inhibiting dental caries, it appears that the tin component must play an important role in bringing about the dental caries reductions noted in this study. The ultimate expansion of the communal water fluoridation program is limited in that it can reach only 50 to 60 per cent of the population at a maximum if every community were fluoridating its water. An effective fluoride dentifrice which can theoretically reach the entire population would be an exceedingly welcome adjunct to preventive dentistry. Furthermore, since this dentifrice contains stannous fluoride rather than sodium fluoride, there is a possibility that it could offer additional benefit to those people using a fluoridated water supply.

It is interesting that the data at the end of 1 year in the college program closely approximated the reduction observed in children who used a similar dentifrice for 1 year. These data, coupled with the previous 2 reports,[8, 9] indicate that a stannous fluoride–containing dentifrice is effective in reducing dental caries experience in both children and adults.

TABLE II

AVERAGE INCREASE IN DENTAL CARIES AMONG "GOOD" AND "POOR" BRUSHERS FOR ONE YEAR PERIOD

DENTIFRICE USED	INCREASE IN TOTAL NEW DMFS		PER CENT REDUCTION IN CARIES RATE FOR GOOD BRUSHING
	POOR BRUSHING	GOOD BRUSHING	
Control	2.032	1.754	13.7
Stannous fluoride	1.299	0.918	29.3
% reduction in caries rate for stannous dentifrice	36.1	47.7	

Since the subjects in this study used the dentifrices according to their individual brushing habits, it was considered important to learn, if possible, what influence the frequency of toothbrushing had upon the effectiveness of the stannous fluoride dentifrice. The "good brushers" were those who brushed their teeth 3 times a day or more; the "poor brushers" were those who brushed 2 times a day or less. The data in Table II indicate that among the control subjects those who had good brushing habits experienced a 13.7 per cent lower caries rate than those who had poor brushing habits; whereas, among the stannous fluoride subjects those who had good brushing habits experienced a caries rate 29.3 per cent lower than those who had poor brushing habits. Also, the stannous fluoride–containing dentifrice was associated with 36.1 per cent reduction in caries rate when used with poor brushing and 47.7 per cent reduction when used with good brushing. Thus, it appears that "good" toothbrushing is more effective against dental caries when performed with the stannous fluoride dentifrice and that the stannous fluoride dentifrice is more effective when applied with "good" toothbrushing.

The data in Table II are derived from subgroups ranging in size from 49 to 107 subjects and are, therefore, considerably less reliable than the total DMFS figure shown in Table I. However, one additional point of considerable interest is apparent in Table II. If the caries rate for the subgroup using the control dentifrice with poor brushing is taken as a base line, it is seen that good brushing alone reduced the caries rate 13.7 per cent, whereas the addition of the stannous fluoride dentifrice alone reduced the caries rate 36.1 per cent. If these two effects were completely additive, the reduction in caries rate as a result of good brushing with the stannous fluoride dentifrice would be 49.8 per cent. The observed effect of the combination of stannous fluoride and good brushing was a 54.5 per cent reduction in caries rate. This is determined by comparing the "poor" brushing–control group with the "good" brushing–stannous fluoride group.

CONCLUSIONS

The effect of a stannous fluoride–containing dentifrice has been studied in a group of university students ranging in age from 17 to 36 years. After using the dentifrice for 6 months there was a 50.4 per cent reduction and at the end of 1 year a 41.6 per cent reduction in caries rate on the basis of new DMF surfaces. In terms of DMF teeth, the reductions were 55.0 and 53.7 per cent at the end of 6 months and 1 year, respectively.

Reductions of 75.1 and 61.1 per cent were found in new DMF surfaces in previously carious teeth, indicating, as in studies on children, that stannous fluoride is quite different from sodium fluoride in its effect on the teeth.

The data indicate that the use of the stannous fluoride dentifrice and the practice of good toothbrushing habits are additive in their effects against dental caries.

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EXHIBIT E

Effect of a dentifrice containing stannous fluoride on dental caries in adults. II. Results at the end of two years of unsupervised use

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Previous attempts to use preventive agents to reduce the dental caries experience in adults were reviewed in a report[1] of an earlier portion of this study. That report also indicated that a stannous fluoride dentifrice in which the abrasive was calcium pyrophosphate effectively reduced the dental caries experience in adults. This finding is in agreement with results from an earlier study showing a similar reduction when the same dentifrice was used by children.[2,3]

The purpose of this paper is to report data which have been obtained after two years of continuous use of a stannous fluoride dentifrice by young adult college students. The present observations are of particular interest since they indicate the possibility that through the use of this type of dentifrice prolonged benefits of topical fluoride therapy may be extended to that portion of the adult population that did not receive the benefits of fluoride in the drinking water while their permanent teeth were calcifying.

EXPERIMENTAL PROCEDURE

A detailed description of the method employed in conducting this study has been reported.[1] Four hundred and twenty-five students from the 1953 freshman class at Indiana University whose ages ranged from 17 to 36 years were given a dental prophylaxis followed by a thorough clinical examination with the aid of complete bitewing roentgenograms. The subjects were then divided into two groups at random after stratification according to previous caries experience. The two groups of young adults were provided with dentifrices which were identical except that one contained 4,000 ppm stannous fluoride. The composition of the dentifrice was identical to that reported previously.[3] Each student reported to the clinic at 6, 12 and 24 months after his initial visit for prophylaxis followed by clinical and roentgenographic examination. The results after 6 and 12 months have been reported.[1]

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Table 1 • Distribution by age of subjects who completed the two year test

Age	Number of subjects	
	Control	SnF_2
18	22	25
19	77	73
20	6	11
21	1	6
22	2	4
23	3	4
24	4	4
25	—	2
26	—	2
27	1	—
Total	116	131

DATA AND DISCUSSION

After a two year period of participation in the dental caries study program, 247 adults were available for re-examination. The age distribution of the subjects completing the test is given in Table 1.

The results, in terms of caries increments, are presented in Table 2. The latter tabulation shows the results of the study in terms of new DMF teeth, new DMF surfaces, and in the components of new DMF surfaces by surface type. The results indicate a reduction in dental caries rate of approximately 30 per cent by all the indices used.

The best over-all estimate of the effectiveness of the stannous fluoride dentifrice is shown in the column in Table 2 labeled "new DMF surfaces." Through the use of this index, a statistically significant reduction of 34 per cent was found in the caries rate. Although this result is not greatly different from that obtained at the end of the first year (42 per cent reduction in DMF surfaces), there is a possibility that the dentifrice decreased in effectiveness on prolonged storage. Because of this possibility, an improved stannous fluoride dentifrice currently is being tested. This dentifrice appears to have a prolonged life and increased anticaries activity, as judged by laboratory tests.

Since the greatest number of subjects were in the 18 and 19 year old age groups (Table 1), it was of interest to determine the effectiveness of the stannous fluoride dentifrice in only these groups. Such a comparison, using the "new DMF surfaces" index, showed a mean caries increment of 5.04 in the control group and

Table 2 • Average increase in dental caries experience in young adults using a stannous fluoride and control dentifrice for a two year period

	New DMF teeth	New DMF surfaces	New DMF surfaces proximal	New DMF surfaces occlusal	New DMF surfaces buccal-lingual
Group 1 116 subjects control dentifrice	1.52	4.99	2.77	1.50	0.72
Group 2 131 subjects SnF_2 dentifrice	1.06	3.31	1.81	0.96	0.54
% reduction in caries rate	30	34	35	36	25
Probability	<0.06	<0.005	<0.007	<0.025	~0.3

Table 3 • Summary of clinical caries tests of dentifrices containing fluoride

Dentifrice combination		Clinical results*	References
Fluoride	Abrasive		
NaF	Calcium carbonate	(−), (−)	5, 6
NaF	Dicalcium phosphate	(−)	7
NaF	Calcium pyrophosphate	(−)	4
SnF_2	Dicalcium phosphate	(−)	8
SnF_2	Calcium pyrophosphate	(+), (+), (+), (+)	1–4

*(−) indicates that no statistically significant protection against caries was observed. (+) indicates that a statistically significant protection against caries was observed.

3.70 in the stannous fluoride group, or a reduction of 27 per cent. This result is consistent with the effect produced by using the entire group for comparative purpose.

Clinical evidence for the anticariogenic effectiveness of a specific dentifrice formulation containing stannous fluoride and calcium pyrophosphate has been presented in this and in four previous reports.[1–4] In contrast, five separate studies indicate the lack of effectiveness for dentifrices containing a combination of fluoride and abrasive other than stannous fluoride and calcium pyrophosphate.

In 1945 Bibby[5] reported no reduction in dental caries among children using a dentifrice containing sodium fluoride and calcium carbonate. Again in 1953 a similar dentifrice was shown by Winkler and co-workers[6] to have no anticariogenic effect among boys 11 to 15 years of age. Another clinical study was later reported by Bibby and Brudevold[7] which showed no reduction among children who used a dentifrice containing sodium fluoride and the conventional dentifrice abrasive, dicalcium phosphate. A fourth study[4] indicated that a sodium fluoride dentifrice was ineffective even though it contained calcium pyrophosphate. The fifth study[8] indicated that a dentifrice containing stannous fluoride was ineffective when the abrasive was dicalcium phosphate, the most commonly used dentifrice abrasive. These studies as a group are summarized in Table 3.

Thus it is seen that a stannous fluoride dentifrice containing calcium pyrophosphate is the only combination of fluoride and abrasive yet tested whose ability to reduce the incidence of dental caries clinically in human beings has been reported.

CONCLUSIONS

After two years of unsupervised use of a dentifrice containing stannous fluoride as the active anticariogenic ingredient and calcium pyrophosphate as the abrasive, a statistically significant reduction in the incidence of dental caries in adults has been observed.

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EXHIBIT F

Caries-inhibiting value of a dentifrice containing stannous fluoride: first year report of a supervised toothbrushing study

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The possible value of stannous fluoride as an anticariogenic agent has been studied for some time. It has been shown to be more effective than sodium fluoride for reducing enamel solubility *in vitro*,[1,2] for reducing dental caries in rats[3-5] and hamsters,[6] and for reducing dental caries in children after topical treatment.[7-9] Moreover, stannous fluoride combined with a compatible abrasive (calcium pyrophosphate) in a dentifrice has already shown an encouraging effectiveness in decreasing dental caries in children and adults.[10-13] Additional clinical studies are needed to verify the results of the dentifrice studies by Muhler and associates. The clinical evaluation study at Bloomington, Minn., has been set up to obtain more information concerning the value of a stannous fluoride-containing dentifrice.

PROCEDURE

Included in the study were 628 children who were in the third and fourth grades at the time of the initial examination in May 1955 and whose parents signed authorizations for participation. These

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children (ages 8 to 11) all received dental examinations by a single examiner with the aid of a portable dental chair, explorers, and a Burton mouth light. Each sound, carious, filled or missing permanent tooth and surface was recorded in code on an examination form designed for the base line and two subsequent examinations. (At the time of the second examination, the first year data on the form were masked to prevent possible unconscious examiner bias in diagnosing.) Two posterior and three anterior bitewing roentgenograms were taken of each child. Any carious surfaces which were subsequently found by the roentgenographic examination were added to the examination forms.

The dentifrice was supplied to the children in plain tubes, with only the label "E" or "H" appearing on the carton. The two dentifrices appeared to be identical in taste, consistency and appearance. They differed only in that one contained 0.4 per cent stannous fluoride and 1 per cent stannous pyrophosphate and had a pH of 4.9; the pH of the control paste was 6.8. The slightly soluble stannous pyrophosphate furnished a reservoir of stannous ions to replace those, derived from stannous fluoride, that may have been inactivated by reaction with other constituents of the formulation. Laboratory evidence[14] indicated that a pH of around 5.0 was most likely to be suitable from the standpoints of stability and effectiveness of stannous fluoride, but that this degree of acidity in a control dentifrice (without stannous fluoride) could introduce a real danger to dental enamel under usage conditions.

The identity of the dentifrice containing the stannous fluoride was unknown to the authors until after the first year anniversary examinations were completed. A sealed letter supplied by the manufacturer and stating the composition (Table 1) of the two dentifrices was opened after the completion of the examinations and the tabulation of data. These formulas are the same as those of the dentifrices tested previously[10-13] with the exception that the "H" dentifrice contained 1 per cent stannous pyrophosphate.

The children at one school received the stannous fluoride dentifrice, whereas those at the other school received the control. The principals at the two schools selected the dentifrice for their schools by the flip of a coin. Each child was given a toothbrush and his designated dentifrice in May 1955 for summer use. More dentifrice was always available at the schools and the children were encouraged to take enough to supply their whole family. The children were shown the proper toothbrushing technic and encouraged to brush their teeth routinely after each meal at home. During the school year 1955-1956 they brushed their teeth under supervision once a day after the noon meal in school.

The relative effectiveness of the "E" and "H" dentifrices and consequently the dentifrice containing 0.4 per cent stannous fluoride was measured by the com-

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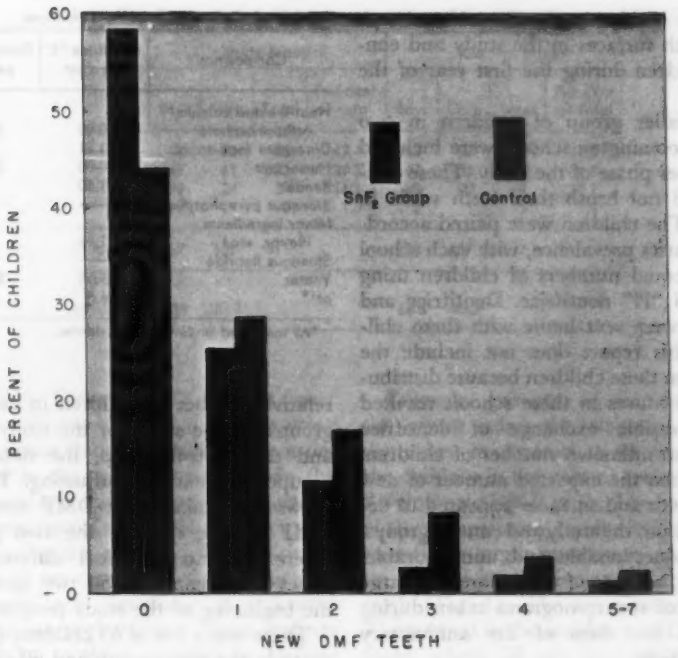

Fig. 1 • Percentage of children with 0-7 new DMF teeth

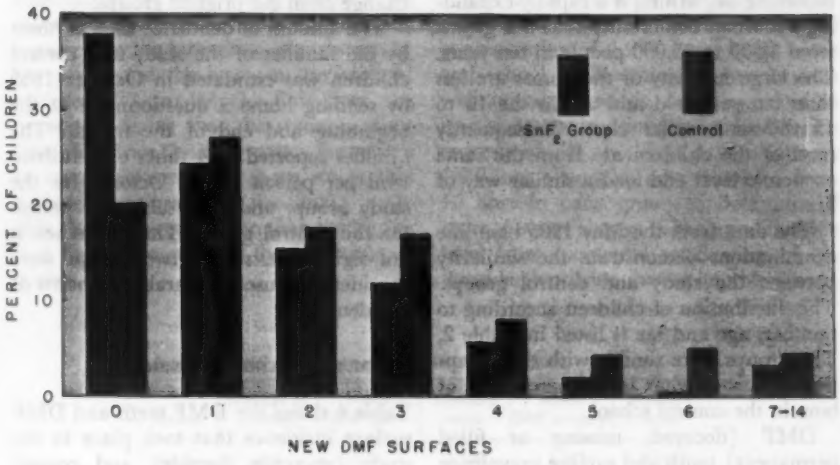

Fig. 2 • Percentage of children with 0-14 new DMF surfaces

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parative incidence of new carious teeth and tooth surfaces in the study and control children during the first year of the study.

A smaller group of children in two other Bloomington schools were included in another phase of the study. These children did not brush their teeth while in school. The children were paired according to caries prevalence, with each school having equal numbers of children using "E" and "H" dentifrice. Dentifrice and brushes were sent home with these children. This report does not include the data from these children because distribution procedures in these schools resulted in a possible exchange of dentifrice among an unknown number of children. Fewer than the expected number of new DMF teeth and surfaces appeared to develop in both the study and control groups. This is questionable and unmeasurable, however, because of the failure of a large number of roentgenograms taken during the last two days of the anniversary examinations.

Table 1 • Composition of the dentifrices

Composition	Dentifrice "E" per cent	Dentifrice "H" per cent
Heat-treated calcium orthophosphate	40.00	39.00
Detergent (non-soap)	1.51	1.51
Humectant	30.00	30.00
Bender	1.50	1.50
Stannous pyrophosphate	——	1.00
Minor ingredients (flavor, etc.)	1.44	1.62
Stannous fluoride	——	0.40
Water	25.55	24.97
pH*	6.8	4.9

*As measured in 25 per cent slurries.

COMPARABILITY OF STUDY GROUPS

Bloomington, Minn., is a rapidly-expanding suburban community that has grown from 3,500 to 35,000 people in ten years. The large majority of the homes are less than ten years old and are in the 10 to 15 thousand dollar class. Consequently most of the children are from the same economic level and lead a similar way of life.

The data from the May 1955 base line examinations demonstrate the similarity between the study and control groups. The distribution of children according to number, age and sex is listed in Table 2. The groups were similar with the exception of a somewhat larger percentage of boys in the control school.

DMF (decayed, missing or filled permanent) tooth and surface prevalence was determined for each group. Since the relative number of children in each age group was the same for the study group and the control group, the data were grouped without age-adjusting. Table 3 shows the similarity of DMF teeth and DMF surface data in the two groups. There was no statistical difference in caries prevalence in the two groups at the beginning of the study program.

There was a loss of 63 children (20 per cent) in the study group and 60 children (19 per cent) in the control group during the first year of the study. A comparison of the initial DMF prevalence of the remaining children showed no significant change from the original groups.

The amount of dentifrice used at home by the families of the study and control children was estimated in October 1955 by sending home a questionnaire at the beginning and end of the month. The families reported 0.34 tubes of dentifrice used per person during October for the study group, and 0.36 tubes per person for the control group. The difference is not significant, so the two groups were considered to use comparable amounts of the dentifrice.

RESULTS AND DISCUSSION

Table 4 shows the DMF teeth and DMF surface incidence that took place in the study (stannous fluoride) and control groups during the calendar year ending in

Table 2 • Distribution of children by age and sex, May 1955

	Study group				Control group			
Age	Boys	Girls	Total	Per cent of total	Boys	Girls	Total	Per cent of total
8	62	73	135	43.4	83	58	141	44.5
9	62	61	123	39.5	67	58	125	39.4
10	26	24	50	16.1	28	20	48	15.1
11	2	1	3	1.0	2	1	3	.9
Total	152	159	311		180	137	317	
Per cent of total	48.9	51.1			56.8	43.2		

May 1956. There were 35 per cent fewer DMF teeth developed in the group using the stannous fluoride dentifrice than developed in the control group. When the DMF surfaces index is used as a method of comparison, the reduction for the group using the stannous fluoride dentifrice is 34 per cent. Both these reductions are statistically significant as indicated by their low probabilities. These findings are similar to those reported by Muhler and co-workers[11, 13] after one year of unsupervised use of a stannous fluoride dentifrice.

There was a greater reduction in the incidence of caries on less susceptible surfaces (Table 5). The greatest reduction occurred on the buccolingual surfaces (41 per cent) and the least on the occlusal surfaces (23 per cent). This does not necessarily mean that the stannous fluoride dentifrice gives greater protection to some surfaces. The more susceptible surfaces (occlusal and proximal) probably need more protection than the buccal and lingual to prevent the incidence of caries.

Fifty-nine per cent of the children in the group using the stannous fluoride dentifrice, in contrast to 44 per cent of the children in the control group, did not develop new DMF teeth. The probability of this occurring by chance is .001. Correspondingly larger numbers of children in the control group developed 1 to 7 DMF teeth (Fig. 1). The same pattern (Fig. 2) occurred in the incidence of DMF surfaces, where 38 per cent of the study group and 20 per cent of the control group did not develop new DMF surfaces. This difference has a probability of less than .0001.

The study dentifrice contained 0.4 per cent stannous fluoride. This is a fluoride concentration of 1,000 ppm. Each home and school in Bloomington has its own well to supply water. Samples taken in four scattered locations showed a fluoride content of .09 to .11 ppm. In January 1956, urine samples were obtained from 40 boys in each group to determine if there was any change in the urine fluoride level from incidental swallowing of the fluoride dentifrice during toothbrushing.

Table 3 • DMF teeth and surfaces: initial examination

Group	Number of children	Mean DMF teeth	Standard error	Mean DMF surfaces	Standard error
Study	248	3.67	0.125	6.20	0.267
Control	257	3.58	0.129	6.24	0.298

Table 4 • Mean DMF incidence, May 1955-May 1956

Group	No. of children	DMF teeth incidence		DMF surfaces incidence	
		Mean	Standard error	Mean	Standard error
Study ($Sn F_2$)	248	0.673	.066	1.488	.113
Control	257	1.043	.077	2.253	.134
Per cent reduction		35.47		33.95	
Probability		<.001		<.0001	

The average fluoride concentration in the urine of the boys using the stannous fluoride-containing dentifrice was 0.198 ppm, whereas the corresponding fluoride concentration from the boys using the stannous fluoride-free control dentifrice was 0.196 ppm. These concentrations were remarkably close, and indicate that there was no increase in the urinary fluoride level resulting from the use of the study dentifrice. These findings corroborate previous work by Schweinsberger and Muhler.[15]

The prevalence of stained teeth in the children using both dentifrices was recorded at the time of the second examination. Forty children had noticeably stained teeth in the stannous fluoride group, and 45 were found with similar staining in the control group. This staining was typical of that found on surfaces that are not self-cleansing in mouths with poor oral hygiene. Casual observations rather than rigid criteria were used in diagnosing "stained teeth."

Five hundred and five, fourth and fifth grade children, equally divided between two elementary schools, provided the control and study groups for the clinical evaluation of a 0.4 per cent stannous fluoride dentifrice. The children in both schools were comparable in age, sex and caries prevalence. Children in both schools brushed their teeth once a day in school after the noon meal, and also received dentifrice and brushes for home care. A mid-year study determined that comparable amounts of dentifrice were being used at home by each group.

The children in the school who used the stannous fluoride-containing dentifrice developed 35 per cent fewer DMF teeth and 34 per cent fewer DMF surfaces than the control children during the first year of the study. These reductions are statistically significant.

A urinalysis in January 1956 showed no elevation in fluoride content in the group using the stannous fluoride-containing dentifrice when compared with the control.

No difference in the prevalence of stain was found in either the stannous fluoride or control group.

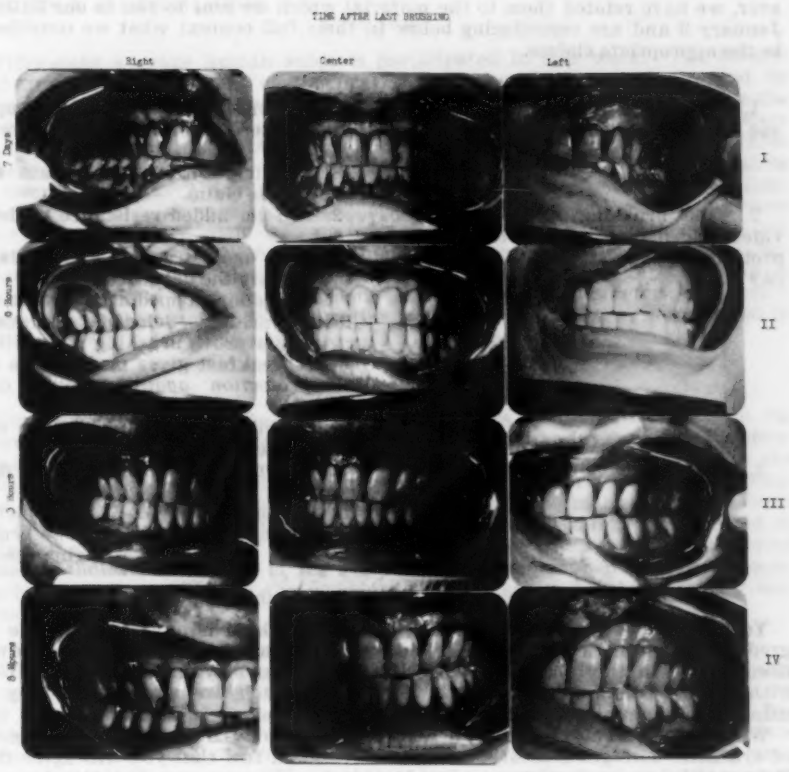
The first year results from the use of this stannous fluoride-containing dentifrice at Bloomington, Minn., corroborate the original work by Muhler and associates in Indiana and show the effectiveness and safety of stannous fluoride used in an abrasive-compatible dentifrice for one year.

15. Schweinsberger, R. A., and Muhler, J. C. Urinary fluorine levels following the clinical use of a stannous fluoride-containing dentifrice. (Abst.) J. D. Res. 34:726 Oct. 1955.

Table 5 • Mean DMF surfaces incidence, May 1955-May 1956

	Number of children	Mean DMFS incidence			
		Proximal	Occlusal	Buccolingual	Total
Study group ($Sn F_2$)	248	.762	.403	.323	1.488
Control group	257	1.187	.521	.545	2.253
Per cent reduction		35.8	22.7	40.7	34.0
Probability		<.001	<.11	<.003	<.0001

EXHIBIT G


TIME AFTER LAST BRUSHING
Right
Center
Left
7 Days
8 Hours
3 Hours
0 Hours
I
II
III
IV

THE PROCTER & GAMBLE CO.,
Cincinnati, Ohio, March 25, 1958.

Hon. JOHN A. BLATNIK,
Chairman, Legal and Monetary Affairs Subcommittee
Committee on Government Operations,
House Office Building, Washington, D. C.

DEAR SIR: Complying with your request of February 20, 1958, we are enclosing clinical data in support of certain Gleem toothpaste claims that you regard as therapeutic in nature. Some of the claims which you quote in your letter have not been used in that exact form in any of our advertising. However, we have related them to the material which we sent to you in our letter of January 9 and are reproducing below in their full context what we consider to be the appropriate claims.

YOUR LETTER OF FEBRUARY 20	FULL CONTEXT
1. "90% reduction of bacteria with one brushing of Gleem"	1. "After one Gleem brushing, up to 90% of these (mouth) bacteria are destroyed." See exhibit 1 for clinical data supporting this claim.
2. "One brushing with Gleem provides 'added resistance to tooth decay, protection against mouth odors all day'"	2. "To get added resistance to decay * * *. protection against mouth odor all day—always start the day with Gleem. "Mouth odor stopped all day with *one* Gleem brushing. Scientific odor-measuring tests prove brushing with Gleem before breakfast gives most people *all-day protection against mouth odor* * * *." See exhibit 2 for clinical data supporting these claims.
3. "Fights decay."	3. a. "Only Gleem has GL-70 to fight decay!" b. "Gleem—with GL-70—completely destroys most bacteria with *one* brushing * * * that's how it fights decay * * *." See exhibit 3.

You state that there is "reference to GL-70, which is advertised as the ingredient providing a 'protective shield against decay.'" We have never advertised GL-70 in this manner. We believe that you may have confused GL-70 with an ingredient of a competitive product which, we understand, may be using claim language similar to that which you quote.

We are reluctant to divulge our exact formula for GL-70, which is the blend of synthetic detergents incorporated in Gleem, and feel that you will agree that it is entitled to protection as a trade secret. However, we are attaching as exhibit 4 a copy of our United States Patent, 2,812,284. Claim 7, column 8, of this patent specifically covers a range of synthetic detergent blends within which the composition of GL-70 falls.

We are pleased to cooperate with your subcommittee by making this material available to you. If there is anything further we can do in this regard, will you please let us know.

Very truly yours,

WM. G. WERNER,
Director, Public and Legal Services.

EXHIBIT H

Claim 1: "After 1 Gleem brushing, up to 90 percent of these (mouth) bacteria are destroyed."

Definitions of essential wording in claim:

". . . *one Gleem brushing*": Brushing the teeth for 60 seconds with a normal amount of Gleem toothpaste. Apart from the time factor, no control was exerted over the manner in which the subjects brushed their teeth. Our length of brushing time was in fact less than the figure of 67 seconds which was given as the average length of brushing time by adults in an article entitled "Toothbrushing Habits of 405 Persons" by Hamilton B. G. Robinson, D. D. S.,

(Journal of the American Dental Association, vol. 33, p. 1112, 1946). The amount of paste used was based on our determination of what is "normal" in studies conducted by our company among 200 individuals.

". . . *up to 90% of these (mouth) bacteria are destroyed*": The maximum number of bacteria removed from the oral cavity 10 minutes after "one Gleem brushing" expressed as a percentage of the number of bacteria in the oral cavity that can be collected and counted.

The support for claim 1 as it is defined above is based on several cumulative studies. One such will be cited here. This study was conducted by an independent research laboratory, Hilltop Research Institute, Inc., William Howard Taft Road, Cincinnati, Ohio.

TECHNIQUE

Fifty-eight average human subjects participated in this work. The before-and-after brushing counts of the oral bacteria population were obtained by having the subjects brush with sterile saline solution and then expectorate the contents of the mouth into sterile jars. Plates for bacteria counting were made from each saline brushing specimen, each specimen being diluted to three different concentrations for plating. The plates were counted after incubating 48 hours at 37° C. A further point on technique may be mentioned. Preliminary experiments showed that toothbrushes used in the saline brushing were heavily contaminated with bacteria even after thorough rinsing under the tap. Immersing the toothbrush for a half-hour in sodium hypochlorite solution containing 50 parts per million available chlorine reduced the bacteria count to a figure negligible in view of the dilutions used for plating. Therefore, a different brush was used in each of the two saline brushings, and these were immersed in sodium hypochlorite solution before being used again.

PROCEDURE

Four sets of "before and after" brushing samples were obtained: One in the morning and one in the afternoon of the first sampling day, one in the morning and one in the afternoon of the second sampling day. Ten minutes after the initial saline brushing to collect a sample of the "before brushing" oral population, the subjects brushed in a normal manner with a normal amount of Gleem for 60 seconds. After another 10 minutes the saline brushing was repeated to obtain the "after brushing" sample. This procedure was repeated three more times as indicated. A total of 229 observations were made with the 58 subjects. Each observation included the complete cycle of saline brushings and Gleem brushing.

RESULTS

With very few exceptions, the bacteria count on the third brushing (second saline brushing) was substantially lower than on the first. In 72 percent of the 229 values obtained, the percent reduction of bacteria was between 60 and 90; 7.6 percent were 90 percent or more. Only 1 of the 58 subjects had an average reduction for the series of four measurements which was less than 50 percent; this value was 33 percent. Three subjects had average reductions of 90 percent or more. Summarized, these data read as follows:

The best 10 percent of the observations showed an average reduction of 92 percent.

The best 15 percent of the observations showed an average reduction of 90 percent.

The best 20 percent of the observations showed an average reduction of 89 percent.

The best 25 percent of the observations showed an average reduction of 88 percent.

The best 30 percent of the observations showed an average reduction of 88 percent.

(See attached bar graph.)

To establish the bactericidal properties of Gleem several in vitro (laboratory) tests have been made. For this procedure, toothpaste is put in saliva collected from caries-susceptible individuals. A low concentration (under 10 percent) of paste is used. The paste and saliva are shaken together for 5 minutes, and then in two steps a 1:10,000 dilution is made, very quickly. A portion of the dilution is incubated with a plating medium for 24 to 48 hours at 37° C. Bacteria counts are made after incubation. Comparison with a control shows that Gleem with GL–70 had definite antibacterial properties.

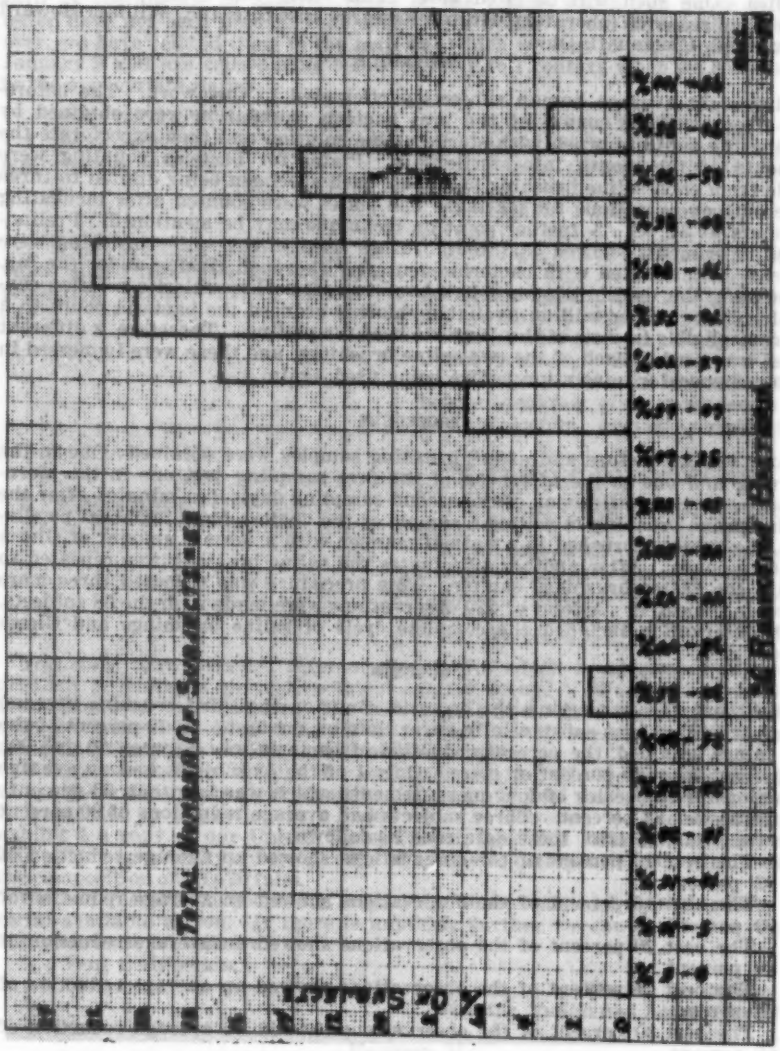

Total Number Of Samples
Excess Of %

EXHIBIT 1

Claim 2: "To get added resistance to decay. * * *"

According to the most widely accepted theory, dental decay is initiated in the following manner: Bacteria, acting upon food debris in the mouth, form a tenacious film on the surface of the teeth called plaque. Enzymes produced by the bacteria convert the refined carbohydrates, such as sugar, in the plaque to acids. These acids attack the tooth surfaces, thus initiating the actual decay. Brushing with Gleem ameliorates conditions that tend to lead to decay, by removing plaque from the teeth and by removing food debris and bacteria from the mouth. Exhibit 1 demonstrates quantitatively the effects of brushing with Gleem on oral organisms.

Claim 2: "To get * * * protection against mouth odor all day—always start the day with Gleem.

"Mouth odor stopped all day with *one* Gleem brushing. Scientific odor-measuring tests prove brushing with Gleem before breakfast gives most people *all-day* protection against mouth odor. * * *"

Clinical experience reported in the literature ("Collective Review—FETOR EX ORE"—M. Massler, D. D. S., M. S.; R. D. Emslie, B. D. S., M. S.; T. E. Bolden, A. B., D. D S; Oral Surgery, Oral Medicine and Oral Pathology, January, 1951) points out that odors originating in the mouth are probably caused by the bacterial putrefaction of food debris and saliva Gleem's mouth odor claims are based on tests carried out by Proctor & Gamble and by Evans Research & Development Corp., 250 East 43d Street, New York, N. Y. Our own work on mouth odor had shown that brushing with Gleem had an effect much greater than could be accounted for by any short-lived masking effect of the flavor ingredients. As a result, we asked Evans, an independent research laboratory with considerable experience in ordor evaluation, to do further work. A trained sensory panel in the Evans organization made 2,425 observations of mouth odor levels. The study was done in three series of evaluations as follows:

1. *Pilot study to test procedure.*—This study was run for 5 consecutive days, during which period the subjects had breakfast as usual but did not brush their teeth with Gleem until after the first, or control, observation for mouth odor was made at 9:30 each morning. As indicated on the attached graph, mouth odor level showed a 2-point drop after brushing with Gleem and remained at a significantly lower level through the day. Thus, mouth odor level went down and stayed down.

2. *Study to measure the effect of no brushing on mouth odor level.*—The second series of evaluations were conducted for 4 consecutive days during which period the subjects did not brush their teeth at all. Observations were made throughout the day to check the level of mouth odor. As indicated on the attached graph, mouth odor level remained high and never went down to the lower level achieved by those subjects who did brush their teeth.

3. *Same study as pilot study, expanded to confirm results.*—The final evaluation with a larger group of subjects ran for 2 consecutive days. The subjects had breakfast at home but did not brush their teeth with Gleem until after the first, or control, observation for mouth odor was made at 9:30 each morning. Additional checks were made throughout the day. As indicated on the attached graph, the mouth odor level showed a drop of almost 3 points after brushing with Gleem and remained at a significantly lower level throughout the day. As in the pilot study, mouth odor level went down and stayed down.

Results showed that where subjects brushed their teeth with Gleem immediately after the 9:30 a. m. control evaluation, the mouth odor level of those subjects was reduced and remained lower at each grading session thereafter. Such a reduction was shown in both the pilot and expanded tests referred to above. It was a reduction which occurred a sufficient number of times to indicate that the lower mouth odor levels were not a matter of chance, but were due to the effects of the brushing with Gleem. Where subjects did not brush their teeth at all for a period of several days, odor levels remained high throughout the day.

In comparisons between people who did not brush their teeth at all and those who did, it was shown that, even where the average initial mouth odor levels were almost identical, the odor levels of those subjects who did brush with Gleem went down and remained at significantly lower levels throughout the day, while the level of those who did not brush remained high.

We deemed it immaterial whether the Evans' tests were conducted before or after the morning meal, because you will notice that the odor in the mouth changed practically not at all after the noon meal. However, we had already conducted a test that substantiates the fact that the mouth odor protection provided by Gleem could be achieved with one brushing before breakfast. A study was conducted among a group of 16 people (6 women, 10 men). They reported to the laboratory as soon as possible after arising and without having eaten, smoked, brushed their teeth, or even taken water. A sample of mouth odor was collected by a method described by Brening, Sulser and Fosdick (Journal of Dental Research, vol. 18, p. 127, 1939). Immediately after the first odor sample was collected, the teeth were brushed with Gleem. The participants then breakfasted and another odor sample was collected. Additional odor samples were collected just before lunch, immediately after lunch, and about 3 hours after lunch.

When all samples had been collected (they were stored at the temperature of solid CO_2 to eliminate any possibility of putrefaction), the samples were graded by a modified Fair-Wells osmoscope which had previously been calibrated and which gave a numerical score of 8 or more to those samples which were considered offensive. This procedure was repeated 1 week later using the same panel.

Of the 16 people on the panel, only 5 provided any samples having a score of 8 (offensive) or more at any time on the same day after having brushed their teeth once (before breakfast) with Gleem. In this study, then, there were 11 out of 16 (7 out of 10) people who, after brushing before breakfast with Gleem, did not have an offensive mouth odor during the day.

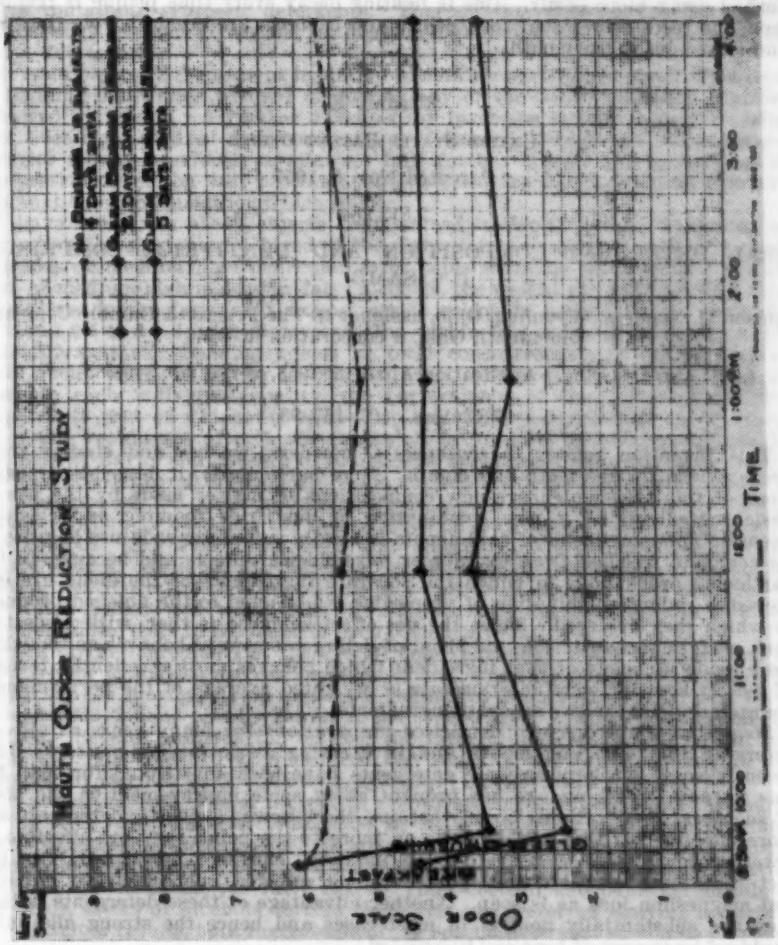

Mouth Odor Reduction Study
Time
Odor Scale

EXHIBIT J

Claim 3: a. "Only Gleem has GL–70 to fight decay!"

b. "Gleem—with GL–70—completely destroys most bacteria with *one* brushing * * * that's how it fights decay. * * *

Gleem (with GL–70) "fights decay" in the manner outlined in attached exhibits 1 and 2. The expression "fights decay" is simply another way of saying that the Gleem action in destroying or removing bacteria can be considered an "added resistance to decay." Gleem helps to remove bacteria from the mouth by lowering surface tension of water and mouth fluids to permit penetration into areas not normally reached with the toothbrush, thus permitting debris to be flushed away more easily. One is fighting decay every time plaque is removed from the teeth or residual food debris and bacteria are brushed from the teeth and rinsed out of the mouth.

EXHIBIT K

UNITED STATES PATENT OFFICE

Patented Nov. 5, 1957

2,812,284

ORAL DETERGENT COMPOSITION AND DENTIFRICE COMPRISING SAME

Judson H. Sanders, Wyoming, Ohio, assignor to The Procter & Gamble Company, Cincinnati, Ohio, a corporation of Ohio

No Drawing. Application April 15, 1953, Serial No. 349,085

7 Claims. (Cl. 167–93)

This invention relates to toothpastes, powders, washes and similar toilet preparations for the teeth and mouth. More particularly, it describes preparations of this type which are new compositions of matter made by the use as basic ingredients of a new combination of dentifrice foaming and cleaning agents. This new blend of said agents is ideally suited for such use because of its complete freedom from toxicity or physiological effects and because, in the particular proportions in which the separate ingredients of the blend are employed, a unique combination of properties is imparted to the finished products in which they are used. Thus, the net effect achieved is that, with respect to each performance criterion, the blend of detergents always behaves as though it were made up solely of that ingredient which behaves most excellently, instead of merely showing some intermediate or weighted average of the performances characteristic of the two separate ingredients.

Soaps have been used in dentifrice preparations for many years as aids in deterging the teeth and mouth and in carrying away foreign matter. More recently some synthetic organic detergents have been substituted for soap for this purpose. This change has brought about some improvement in the taste of such oral preparations, largely because these newer synthetic detergents are more effective foamers and cleaners or, more to the point, they are effective at lower concentrations than soap. This improved efficiency is due partly to the fact that these synthetic detergents are not affected appreciably by calcium and magnesium ions as is soap. Another advantage of these detergents is that they are substantially neutral in most cases and hence the strong alkalinity produced by the use of soap can be avoided.

In spite of these advantages which have been produced by the substitution of synthetic organic foaming agents for soap, none of these new synthetic foaming agents which have thus far been proposed for use in oral preparations have been completely satisfactory for this purpose. Thus, all of these materials are still relatively harsh or strong in flavor compared to the other necessary ingredients of dentifrices. Largely because of these unpleasant detergent flavors, it has been customary in the past to add the essential flavoring oils in amount which are in considerable excess of that required to impart a truly pleasant and refreshing taste to the product. This results in a very high level of total flavor which produces intense and burning taste sensations in the mouths of many persons instead of the feeling of refreshments which can be created by use of

these essential oils at the proper concentration. Also, many synthetic foaming agents are worse than soap in the matter of flavor reactions with certain foods, such as citrus fruits and coffee. Apparently this effect is due to the adsorption of these agents on the mouth tissues during use and their resultant adverse flavor reactions with foods eaten within the period of effective adsorption. Frequently these flavor reactions are very unpleasant, particularly when the foods are acidic in nature as is the case with fruits and their juices, foods which are very commonly taken shortly after brushing the teeth.

In copending application Serial No. 311,303 now abandoned which was filed in the U. S. Patent Office by Wilfred S. Martin on September 24, 1952, there is disclosed a solution to the taste problems commonly encountered in dentifrices containing synthetic detergents. This solution involves the use of sulfonate salts of monoglycerides of medium-high molecular fatty acids as the active detergent.

It is an object of the present invention to obtain even greater speed of sudsing in foaming dentifrices without sacrificing any of the improved flavor qualities achieved by Martin. A further object of my invention is to provide a foaming dentifrice characterized by a combination of flavor mildness and sudsing speed superior to any previously available. Still further objects and advantages of the present invention will become apparent from the detailed description and explanation of the invention which follow.

I have found the above objects are attained in dentifrices by employing as the active foaming agent a blend of the water-soluble sulfonate salts of monoglycerides of medium high molecular fatty acids with the water-soluble sulfate salts of medium-high molecular fatty alcohols, the weight ratio of the fatty alcohol sulfate to the fatty acid monoglyceride sulfonate being between about 0.2 to 1 and 0.5 to 1. I have discovered that within this range of proportions this blend of synthetic foaming agents at total concentrations in the product of from about 0.60% to 3% by weight performs synergistically in that, with respect to each individual quality, the performance of the blend always corresponds to that of whichever of the two individual detergents is superior and all of the weaknesses of each one separately are thereby eliminated. Thus, the mildness of flavor and absence of unpleasant flavor reactions with foods, which are characteristics of the monoglyceride sulfonate detergent, prevail in spite of the presence of the alkyl sulfate material while the sudsing pattern of the blend surprisingly combines the initial speed of the alkyl sulfate detergent with the copious, high-level production and stability of the monoglyceride sulfonate sudser. As a result, there can be obtained in accordance with this invention dentifrice products, which are not only truly mild-flavored and free of any taste defects but which also provide an optimum foaming and cleaning effect from the start to the finish of each period of use.

Each of the ingredients of the special detergent blend which I have found so effective for dentifrice use can be made by well known procedures. Methods of preparing the monoglyceride sulfonate ingredient are given by Clark in U. S. Patent 2,006,309 and also by Martin in his copending U. S. application Serial No. 311,303. Several methods for making the fatty alcohol sulfate ingredient are available. Representative procedures and some of the better techniques are disposed by Bertsch in U. S. Patents 2,264,737; 2,047,612 and 1,968,794.

In preparing each type of ingredient for my special detergent blend the source of the fatty raw material is selected in such a manner as to provide fatty hydrocarbon chain structures which are predominantly saturated and of medium-high molecular weight. By "medium high molecular" is meant containing from 10 to 18 carbon atoms per fatty chain. Thus, coconut and palm kernel oils or the acids, esters or alcohols derived therefrom are preferred starting materials. For optimum results, both ingredients of my special detergent should be prepared predominantly from raw materials possessing saturated fatty hydrocarbon chains predominantly of from 12 to 16 carbon atoms in length.

I have found that by employing the sodium salts of sulfated fatty alcohols of medium high molecular weight in the proportions of 1 part by weight to 2–5 parts by weight of sodium sulfonate monoglycerides of medium-high molecular weight, 0.6% to 3% by weight of the resulting mixture can be incorporated into a dentifrice which is very mildly flavored with added essential oils without causing any unpleasant aftertaste of its own or changing the taste of foods which are eaten shortly after brushing with the said dentifrice. Moreover, in addition to this ideal performance from the point of view of flavor standards, the detergents of my particular blend complement each other perfectly in the

matter of sudsing behavior. Thus, the suds level of a dentifrice containing a certain concentration of my combination detergent gives more foam at the start of sudsing than one containing the same concentration of pure monoglyceride sulfonate and more foam during the intermediate and final stages of use than one containing the same concentration of fatty alcohol sulfate. This superiority of my special detergent blend over the separate individual ingredients, as well as another of the better dentifrice detergents now in use, is demonstrated by the results below which were obtained from comparison tests of toothpastes which differed from one another only as to the character of the detergent.

The composition of each of the test dentifrices was made to correspond to the following general formula:

Ingredient:	*Parts by Weight*
Dicalcium phosphate abrasive	42.83
Water-Glycerin Elixir	53.00
Irish Moss Binder	1.45
Std. Mint Flavoring	0.72
Detergent	2.00
Total	100.00

The detergent in paste K was sodium coconut monoglyceride sulfonate; in paste L it was sodium alkyl sulfate derived from coconut oil alcohols; and in paste M it was a blend of these two individual detergents in the proportion of 3 parts sodium coconut monoglyceride sulfonate to 1 part sodium alkyl sulfate derived from coconut oil alcohols. Both of the detergent products prepared for use in the above compositions were purified by extraction and recrystallization to remove inorganic salts and other impurities. The final products which were incorporated into the toothpastes contained about 90% active organic detergent in each case.

The pastes described above were compared, (1) for effect on the flavor of orange juice consumed after use of paste and (2) for sudsing characteristics. The particular comparison tests employed and the results obtained therefrom are described below.

(1) *Orange juice flavor effect test.*—A panel of 21 persons was checked for this taste reaction. Each person compared the taste of a standard brand of orange juice before and after using the test paste. Each person gave a numerical rating to the test paste of from 0 to 3 depending upon the amount of added bitterness imparted to the orange juice flavor after using the paste. The rating scale was standardized on the following basis:

0—no added bitterness
1—slight added bitterness
2—medium added bitterness
3—strong added bitterness

Representative results from a number of these tests of the effect of the pastes on orange juice are given below:

Paste	No. of Subjects	No. Detecting Some Bitterness	Percent of Subjects Detecting Bitterness	Average Bitterness Score per Subject
K	20	11	55	0.70
L	21	20	95	1.76
M	21	11	52	0.76

In spite of the wide difference between straight monoglyceride sulfonate paste (K) and straight alkyl sulfate paste (L) in both incidence and severity of flavor reaction with orange juice as shown by the results above, the performance of paste M containing the 3 to 1 blend of these detergents is seen to be comparable in both of these respects to that of the straight monoglyceride sulfonate paste (K).

(2) *Sudsing characteristics.*—The sudsing performance of the several pastes was determined by a graduate shaking test. In this test 1.4 grams of the paste being evaluated were smeared into the bristles of a sawed-off tooth brush head which was then dropped into 100 cc. of Cincinnati tap water at 90° F. in a 250 cc. graduate. This water contained hardness equivalent to about 175 p. p. m. $CaCO_3$.

The graduate was then covered and shaken by hand with a vigorous up and down motion. Readings of the foam volume thus produced were made after each 5 complete shakes. Results were as follows:

No. of Shakes	Foam Volume (cc.)		
	Paste K	Paste L	Paste M
0	0	0	0
5	70	87	87
10	121	90	121
15	143	80	147
20	153	46	160
25	166	30	167
30	174	30	174
35	174	37	174
40	183	43	177

These tests were quite reproducible and substantially the same results were obtained by several different operators. The above results indicate that paste M, which contains the blend of detergents, produces foam with all the speed of the straight alkyl sulfate paste (L) but has combined therewith the continuous high level foam production and foam stability of the straight monoglyceride sulfonate paste (K). Thus, the level of suds production with paste M is better than that from paste K at the start and equal to that of K thereafter, while paste M equals paste L in foam production at the start but does not fall off and become unstable thereafter as L does.

In view of the results of the above comparisons, it is apparent that a toothpaste containing the mixture of detergents is superior overall to pastes made up with an equal amount of either one of the individual detergents by itself. Thus, paste M containing the blend has a definite advantage over the alkyl sulfate paste (L) both in freedom from taste reactions with citrus fruits and other foods and in overall sudsing performance. Against the straight monoglyceride sulfonate paste (K), the mixed detergent paste (M) shows up about equal on flavor effects but definitely superior on overall sudsing behavior due to its quicker pickup in initial foam production. These same advantages of combining the two detergents in one product are found at all concentrations of the blend from 0.6 to 3.0% provided the composition of the blend lies between about 17–33% alkyl sulfate and 83–67% monoglyceride sulfonates.

Although the advantage of my particular detergent blend over the straight sodium coconut monoglyceride sulfonate alone resides chiefly in this one point of increased sudsing speed, it is nonetheless a very valuable and desirable improvement and it is very significant to note that it was achieved without loss or reduction in the other very desirable characteristics which characterized sodium coconut monoglyceride sulfonates alone and which made these materials almost ideal for use in dentifrices, such as mildness in flavor, freedom from taste reactions and stability or inertness to other ingredients.

Since my particular detergent blend is neutral, nontoxic and unaffected by calcium, magnesium or other metallic ions and inorganic salts, there are no special problems involved in selecting companion ingredients for use therewith. However, the following examples illustrate typical compositions which may be prepared in accordance with the present invention.

Example I

A typical toothpaste formulated in accordance with the present invention is the following:

Ingredient:	*Parts by Weight*
Dicalcium phosphate	40.88
Sodium monoglyceride sulfonate	2.30
Sodium alkyl sulfate	0.70
Water-glycerine elixir	53.00
Saccharine	0.12
Irish Moss Extract	2.00
Flavor (Mint)	1.00
Total	100.00

Example II

Another composition for a toothpaste which makes full use of the advantages of the present invention is the following:

Ingredient:	*Parts by Weight*
Dicalcium phosphate	43. 155
Sodium Monoglyceride Sulfonate	0. 750
Sodium alkyl sulfate	0. 375
Water-glycerine elixir	53. 000
Irish Moss Extract	1. 500
Salt and Sweetener	0. 370
Flavoring	0. 850
Total	100. 000

Both of the pastes of Examples I and II above are products of exceptionally high quality and are characterized by mild refreshing flavor, ideal sudsing behavior and freedom from interference with the flavor of other materials which may contact mouth surfaces which have been cleaned therewith. Moreover, these products are very stable and may be stored for periods of a year or more even under adverse temperature conditions without loss of these desirable characteristics. The same advantages are found when potassium or other alkali metal salts are substituted for the sodium salts in the above examples. Ammonium and substituted ammonium salts could also be used.

The composition of Example II is extremely mild and pleasant to taste and especially well liked by children and others with sensitive mouth tissues. In spite of the fact that this product contains less added flavoring than most popular brands of toothpaste now on the market, its overall superiority has been consistently demonstrated in several home use tests in blind competition with the two best selling competitive products. These home use tests are made by giving a sample of the product of Example II and a sample of the competing commercial product, each packaged in plain white tubes with letter-code identification only, to each person surveyed. All persons surveyed in these home use tests still possessed their own natural teeth and claimed to be regular users of commercial dentifrices.

The results of the largest of the above tests with each competitive product are given below:

TEST 1—EXAMPLE II PASTE VS. BEST SELLER NO. 1

Out of nearly 700 people surveyed 58% of all those expressing a preference favored the composition of Example II overall (56% of the adults and 61% of the children). On the basis of foaming qualities alone, 57% of the adults expressing a choice voted for the Example II paste. On the basis of flavor alone the product of this invention was preferred by 60% of both the children and adults expressing a choice.

TEST 2 EXAMPLE II PASTE VS. BEST SELLER NO. 2

Out of nearly 700 people surveyed 58% of all those making definite overall choice voted for the composition of Example II, (54% of the adults and 66% of the children). On the basis of foaming qualities alone, 57% of the adults expressing a choice voted for the Example II product. On the basis of flavor alone, the figures for the product of this invention were 59% of the adults and 72% of the children.

It will be apparent that my invention is susceptible to almost unlimited variations as regards choice of other ingredients to be used with my blend of detergents in forming the various oral preparations. Thus, any of the other well known polishing compounds such as calcium carbonate, magnesium hydroxide, calcium sulfate, aluminas, tricalcium phosphate and other calcium phosphates may be substituted for the dicalcium phosphate shown in the above examples. Starch, natural and synthetic gums, and many other binders may be used in place of Irish Moss and similar substitutions as are known in the art of dentifrice making may be effected throughout the above formulae. Oil of wintergreen, oil of cloves, oil of cinnamon and any other essential oils or flavorings suitable for use in dentifrices may be used in place of the mint flavoring shown in the above examples and in all cases a reduced amount will be found

necessary to produce a given flavor effect, and a cleaner, fresher tasting paste can be produced as a result of this fact. In addition to the indicated substitutions, many additional materials may also be incorporated into the dentifrice for specific purposes, such as germicides or therapeutic agents, special adsorbents or coloring agents, etc. All such variations are intended to be included within the scope of the appended claims.

Having thus described my invention, what I claim and desire by Letters Patent is:

1. A dentifrice having a superior initial sudsing speed and improved flavor qualities and containing between about 0.6% and 3.0% by weight of a mixture of water-soluble salts of fatty acid monoglyceride sulfonates containing from 10 to 18 carbon atoms per fatty chain and water-soluble salts of fatty alcohol sulfates containing from 10 to 18 carbon atoms per fatty chain in which the weight ratio of the salts of fatty alcohol sulfates to the salts of fatty acid monoglyceride sulfonates is between about 0.2 and 0.5.

2. A dentifrice having a superior initial sudsing speed and improved flavor qualities and containing between about 0.6% and 3.0% of a mixture of synthetic organic detergents, said mixture being composed of from about 17 to 33% by weight of water-soluble salts of fatty alcohol sulfates containing from 10 to 18 carbon atoms per fatty chain and from about 83 to 67% by weight of water-soluble salts of fatty acid monoglyceride sulfonates containing from 10 to 18 carbon atoms per fatty chain.

3. A toothpaste having a superior initial sudsing speed and improved flavor qualities and containing as the active foaming agent about 0.6 to 3% of a blend of the sodium salts of fatty alcohol sulfates containing from 10 to 18 carbon atoms per fatty chain and the sodium salts of fatty acid monoglyceride sulfonates containing from 10 to 18 carbon atoms per fatty chain in the proportions of 0.2 to 0.5 part by weight of the fatty alcohol sulfates per part of the monoglyceride sulfonates.

4. A dental preparation having a superior initial sudsing speed and improved flavor qualities and comprising a polishing agent, a flavoring agent, a flavoring material and between about 0.6% and 3.0% of a mixed detergent containing 2 to 5 parts by weight of sodium monoglyceride sulfonates of predominantly saturated fatty acids of from 10 to 18 carbon atoms in length per part of sodium salts of predominantly saturated sulfated fatty alcohols of from 10 to 18 carbon atoms in length.

5. A toothpaste having a superior initial sudsing speed and improved flavor qualities and comprising about 40 to 60 parts by weight liquid vehicle, about 1 to 2 parts by weight Irish Moss extract, about 30 to 50 parts by weight of a calcium phosphate polishing agent, about 0.5 to 1.2 parts by weight flavoring material, and about 1 to 2 parts by weight of a detergent blend composed of about 67 to 83% by weight of sodium monoglyceride sulfonates of predominantly saturated fatty acids of from 10 to 18 carbon atoms in length and about 33 to 17% by weight of sodium salts of predominantly saturated sulfated fatty alcohols of from 10 to 18 carbon atoms in length.

6. A mildly flavored but copiously foaming toothpaste containing as the active foaming agent about 1 to 2 parts by weight of a detergent blend composed of about 67 to 83% by weight of sodium monoglyceride sulfonates of predominantly saturated fatty acids of from 10 to 18 carbon atoms in length and about 33 to 17% by weight of sodium salts of predominantly saturated sulfated fatty alcohols of from 10 to 18 carbon atoms in length and about 0.5 to 1.2 parts by weight of flavoring material.

7. A detergent blend especially suitable for use in dentifrices to promote superior initial sudsing speed and impart mild flavor characteristics the active portion of which is composed of from about 67 to 83% by weight of sodium monoglyceride sulfonates of predominantly saturated fatty acids of from 10 to 18 carbon atoms in length and about 33 to 17% by weight of sodium salts of predominantly saturated sulfated fatty alcohols of from 10 to 18 carbon atoms in length.

References Cited in the file of this patent

UNITED STATES PATENTS

2,006,309	Clark	June 25, 1935
2,264,737	Bertsch	Dec. 2, 1941
2,519,665	Klippert	Aug. 22, 1950
2,556,959	Connelly	June 12, 1951

FOREIGN PATENTS

644,339	Great Britain	Oct. 11, 1950

31755 O—58——12

JULY 17, 1958.

Commenting on testimony before the Blatnik subcommittee, Procter & Gamble spokesman said:

"Procter & Gamble obviously agrees with the ideal for dental care set by the American Dental Association. We agree that brushing your teeth after every meal is best and have said this—in just these words—literally billions of times. Every Gleem advertisement carries this statement at least once.

"But we also know that, despite the program of the ADA and the prominence toothpaste advertisers have given this message, most people just don't brush their teeth after every meal. (And, unless they carry a toothbrush around in their pockets, a great number of people can't brush after every meal.)

"Precise information on the frequency with which people brush their teeth is difficult to get because people tend to overstate their good habits when they talk to an interviewer. But even with this distortion, research indicates that less than 10 percent of the American people brush their teeth 3 times a day and that the average number of brushings for the population as a whole is about 3.58 times a week—about once every 2 days. We also know that about 18 percent of the population do not brush their teeth at all. Some of these, of course, are infants and people with dentures but a sizable part of this 18 percent just never brush their teeth.

"Marked progress is being made in improving the general standards of dental care, however. In 1939, for instance, residents of the United States brushed their teeth an average of 0.67 time per week; today, as we've said, the average has risen to 3.58 brushings a week. It is significant, we think, that this rise in the level of dental care parallels the increase in all dentifrice advertising expenditures during this period.

"Gleem advertising says that just one brushing destroys decay- and odor-causing bacteria and for most people gives all-day protection against mouth odor. There is no question about the validity of these claims. The clinical evidence which we have submitted to Mr. Blatnik's subcommittee supports these statements and documents this product's superior performance in these specific ways.

"In our advertising for this toothpaste, it would be foolish for us not to publicize the proven superior performance of the product and to relate its benefits to the toothbrushing habits of the American people as we know them.

"There is nothing 'misleading' about this advertising. Convincing evidence that it is not detrimental to the public interest can be found in the rising standards of dental care in this country. It is unfortunate that the ADA has chosen to question this advertising since we feel that we are both working toward the same goal—that we both have a considerable stake in improving the standards of tooth care in this country."

EXHIBIT 3

DECEMBER 11, 1957.

MR. FRANK A. SPROLE,
Secretary, Bristol-Myers Co., New York, N. Y.

DEAR MR. SPROLE: Thank you for your letter of November 12 and the advertissing copy for Ipana toothpaste. I note that the advertising submitted includes several therapeutic claims, namely:

"New Ipana with WD–9 has twice the decay germ-killing power of any other leading toothpaste."

"New Ipana with WD–9 destroys decay bacteria better than any other leading brand—including fluoride toothpaste."

"Not a whisper of bad breath."

"Look, laboratory tests prove it!"

"Use Ipana regularly. It prevents bad breath."

"WD–9 is a terrific decay fighter. Ipana with WD–9 destroys decay bacteria best of all leading brands, including fluoride toothpastes."

In my letter of October 31, I asked, "In addition, where therapeutic claims are made in such advertising, I would appreciate receiving the clinical data on which such claims are based."

May I have this data at your earliest convenience?

Sincerely yours,

JOHN A. BLATNIK.
Member of Congress, Chairman.

BRISTOL-MYERS CO.,
New York, December 31, 1957.

Hon. JOHN A. BLATNIK,
Chairman, Legal and Monetary Affairs Subcommittees of the Committee on Government Operations, House of Representatives, Washington, D. C.

MY DEAR CONGRESSMAN: In reply to your letter of December 11, 1957, we wish to advise that the data on which the claims quoted in your letter are based will be furnished to you shortly. Owing to the holiday season there has been a delay in gathering this material together.

The statements set forth in your letter fall to into two categories: (1) those concerning new Ipana's efficacy as a killer of decay germs; and (2) its efficacy in preventing bad breath. As neither of these is a therapeutic claim (the first is bacteriological and prophylactic, rather than curative; the second is merely cosmetic), we did not take it that information concerning them had been sought by your letter of October 31. However, now that you have expressed a desire to receive this material, we shall be pleased to furnish it.

Very truly yours,

FRANK A. SPROLE, *Secretary.*

MICROBIOLOGICAL LABORATORY REPORTS IN SUPPORT OF IPANA ANTIBACTERIAL CLAIMS

Bristol-Myers Products Division, Bristol-Myers Co., 225 Long Avenue, Hillside, N. J.

A. ZONE OF INHIBITION STUDIES

(In support of, "Kills decay bacteria better than any other leading dentifrice.")

In these tests, a uniform suspension of bacteria is plated out onto the surface of a nutrient medium (Trypticase soy agar). A filter disk is impregnated with 0.2 gram of the test dentifrice and placed on the surface of the agar plate which is then incubated. The clear zone surrounding the disk after incubation shows a lack of bacterial growth in that area, and is proportionate to the degree of antibacterial activity of the sample.

Tables I through VII show the results of tests run on different occasions over the past 2½ years. They indicate the comparative activity of Ipana and 10 other dentifrices, including the major regular and fluoride pastes currently being marketed. Each figure represents the average of 3 to 5 samples, and each is written a±5 percent range. (The apparent lack or uniformity in absolute values from table to table is due to uncontrollable differences in the bacterial concentration of the various plating suspensions. The relative superiority of Ipana, however, remains constant.)

TABLE I

	Str. salivarius	*L. casei*		Str. salivarius	*L. casei*
Ipana	8.3	15.3	F	0	3.0
A	0	3.0	G	0	1.0
B	3.3	10.6	H	2.0	9.3
D	0	0	J	1.6	4.3

TABLE II

	Str. salivarius	*L. casei*		Str. salivarius	*L. casei*
Ipana	3	8	H	1	6
E	1	4	K	0	4
G	0	4			

TABLE III

	Str. salivarius	L. casei
Ipana	7	13
E	3	10

TABLE IV

	Str. salivarius	L. casei		Str. salivarius	L. casei
Ipana	2	14	F	0	9
C	0	8	G	0	6
E	0	11	H	1	10

TABLE V

	L. casei		L. casei
Ipana	11	F	7.5
B	7	G	4
E	6.5	H	7

TABLE VI

	L. casei		L. casei
Ipana	10	E	10
G	7	H	9

TABLE VII

	L. casei		L. casei
Ipana	7	G	5
B	6	H	7
E	5		

B. SERIAL DILUTION STUDIES

(In support of, "Ipana has twice the decay-germ-killing power of any other leading toothpaste.")

Serial dilution tests were embarked upon to obtain comparative information of a quantitative nature. These tests involved a comparison of the antibacterial effects of Ipana and the five leading competitive dentifrices. Varying amounts of toothpaste were mixed with keratin particles in combinations ranging from 93 percent paste/7 percent keratin down to 5 percent paste/95 percent keratin.

The keratin-paste mixtures were then added to test tubes containing cultures of Lactobacillus casei, nutrient broth, and Snyder indicating medium and were incubated according to the methods utilized in the Fosdick antienzyme tests. Table I shows the results of this experiment.

Subsequent testing (table II), utilizing concentration intervals of 2.5 percent, showed that the minimum amount of paste effectively inhibiting bacterial action (acid production) was Ipana 10 percent, competitive products 22.5 percent or higher (none of these latter pastes were effective at the 20 percent level). On the basis of these results a statistical program was set up and table III indicates the results of multiple tests.

The concentrations designated in the keratin-paste mixtures were verified by the analytical laboratory to prevent any possible variables due to errors in the mechanical mixing techniques as shown in table IV.

TABLE I.—*Acid inhibition obtained with varying concentrations of dentifrices*

	Percentages					
Keratin	87.5	75	50	25	12.5	6.25
Paste	12.5	25	50	75	87.5	93.75
Ipana	+	+	+	+	+	+
B	−	+	+	+	+	+
E	−	+	+	+	+	+
F	−	−	−	+	+	+
G	−	−	−	+	+	+
H	−	−	−	+	+	+

+=inhibition of acid production.
−=no inhibition

TABLE II.—*Acid inhibition study (narrower dentifrice concentration ranges)*

	Percentages									
Keratin	92	90	87.5	85	82.5	80	77.5	42.5	40	37.5	35
Paste	8	10	12.5	15	17.5	20	22.5	57.5	60	62.5	65
Ipana	−	+	+	+	+	+	+				
B		−	−	−	−	−	+				
E		−	−	−	−	−	+				
F								−	−	−	+
G								−	+	+	+
H								−	−	−	+

TABLE III.—*Repeat tests for statistical verification (1 negative in 9 acceptable)*

	Keratn	Paste	Test No.								
			1	2	3	4	5	6	7	8	9
Ipana	90.0	10.0	+	+	+	+	+	+	+	+	+
B	77.5	22.5	+	+	+	+	+	+	+	+	+
E	77.5	22.5	+	+	+	−	+	+	+	+	+
F	35.0	65.0	+	+	+	+	+	+	−	+	+
G	40.0	60.0	+	+	+	+	+	+	+	+	+
H	35.0	65.0	+	+	+	+	+	+	+	+	+

+=inhibition of acid production.
−=no inhibition.

TABLE IV.—*Analytical verification of dentifrice concentrations in sample dentifrice-keratin mixtures*

	Percentage of paste designated	Percentage of paste found
Sample, dentifrice-keratin	10	10.6
Do	22	22.6
Do	35	35.4

CLINICAL REPORT IN SUPPORT OF IPANA BREATH-CONTROL CLAIMS

Dr. Louis C. Barail, New York, N. Y.

In the following report on the mouth-odor controlling properties of Ipana, Dr. Barail has followed the protocol established in earliier quantitative studies. The level of mouth odor considered offensive (based on extensive previous experience and testing) has been assigned a numerical value of 8.6 so that only those values above this figure fall in the objectionable range. To make this a valid test of odor-controlling properties, only subjects presenting initially with a level substantially above 8.6 were accepted for this study.

REPORT INVESTIGATION OF THE DEODORIZING PROPERTIES OF IPANA

The purpose of this study was to establish the efficiency of Ipana toothpaste in removing mouth odors of local origin after various periods of time.

SELECTION OF SUBJECTS

Fifty subjects of both sexes participated in this investigation. Twenty-six males and twenty-four females were selected from a greater number of individuals in order to meet the following requirements:

1. The original odor threshold numbers (OTN's) of the mouth odor before brushing the teeth should be above 8.6, therefore above average.
2. The odor should be due to local causes only. In order that the odor to be measured could not be attributed to any extraneous causes, the 50 subjects were instructed not to eat spicy foods or condiments during the day preceding the tests. They were not allowed to brush their teeth before the first OTN determination.

BRUSHING AND RINSING PROCEDURE

Each subject was given a Tek medium toothbrush and a tube of Ipana. Approximately one gram of dentifrice was evenly applied on each brush. He then brushed his teeth in his usual manner for 45 seconds, rinsed his mouth three times with approximately 1½ ounce of water each time, and rinsed his toothbrush in running water. He brushed his teeth again for 30 seconds, rinsed his mouth thrice as before and was dismissed until the next odor threshold number determination. Brushing and rinsing were timed by means of a stopwatch.

SAMPLING OF MOUTH ODOR

The sampling was made in 50 cubic centimeter flasks stopped with odorless plastic stoppers terminated with glass tubing. Each flask was connected to a 50 cubic centimeter syringe and introduced in the mouth by placing the glass tubing at the left commissure of the lips while a Tygon tubing was placed at the right commissure to allow the inflow of air from the outside while the air in the mouth was being pumped into the syringe.

TESTING PROCEDURE

Each sampling flask was connected immediately to the new Barail Osmagraph (R) and odor threshold numbers were measured without delay. Such measurements were made before brushing, and 4 and 9 hours after brushing. Record was made of smoking during the day.

The following table gives the results of this investigation.

Subject's identification	Original odor threshold number	Smoked	Odor threshold number after—	
			4 hours	9 hours
1. E. B. (male)	12.1	Yes	3.37	8.6
2. L. P. (male)	11.7	Yes	3.95	6.5
3. J. S. (male)	10.1	No	0	0
4. S. W. (female)	9.5	Yes	5.0	8.6
5. M. H. (male)	13.0	Yes	3.95	6.2
6. J. T. (male)	12.1	No	4.55	8.6
7. L. L. (male)	12.1	No	0	0
8. J. W. (male)	10.7	Yes	3.79	5.68
9. S. P. (female)	13.0	Yes	4.33	6.5
10. A. S. (male)	12.1	Yes	4.55	7.0
11. F. G. (female)	12.1	No	0	0
12. B. B. (female)	10.7	Yes	3.79	5.68
13. M. K. (male)	14.0	No	5.87	8.6
14. S. M. (male)	9.5	No	0	3.95
15. D. G. (male)	12.1	No	0	0
16. E. P. (female)	10.7	No	0	5.68
17. R. H. (female)	12.1	No	0	5.87
18. H. H. (male)	9.5	No	4.33	6.5
19. P. R. (female)	12.1	No	3.79	5.68
20. L. R. (male)	11.7	No	0	0
21. S. Sch. (male)	8.6	No	0	3.95
22. F. S. (female)	9.5	Yes	3.37	4.91
23. F. M. (female)	8.6	No	0	0
24. M. P. (male)	9.1	Yes	4.33	5.68
25. H. G. (male)	10.1	No	0	6.7
26. C. F. (male)	9.5	No	3.79	5.25
27. E. C. (male)	10.7	No	4.33	4.33
28. S. H. (female)	8.6	No	0	0
29. D. S. (female)	9.5	No	0	5.87
30. S. St. (male)	8.6	Yes	4.15	6.5
31. S. L. (male)	10.7	Yes	3.79	4.55
32. E. S. (male)	9.1	Yes	4.55	6.5
33. L. T. (female)	9.6	No	0	0
34. S. S. (female)	10.1	No	0	4.13
35. J. D. (male)	10.7	No	3.79	6.5
36. M. K. (female)	8.6	No	0	0
37. L. W. (male)	9.6	Yes	0	7.0
38. P. H. (male)	10.1	No	3.37	5.68
39. P. C. (female)	10.1	No	4.33	6.5
40. A. P. (female)	9.5	No	0	0
41. F. M. (female)	10.7	No	3.37	7.0
42. H. R. (female)	8.6	No	0	4.33
43. C. K. (male)	9.6	No	0	0
44. P. D. (female)	12.1	No	3.95	8.6
45. R. D. (female)	13.0	No	5.87	9.5
46. G. B. (female)	9.5	Yes	0	0
47. D. O. (female)	11.7	No	5.0	7.0
48. M. D. (female)	10.7	Yes	0	0
49. W. Z. (male)	8.6	No	3.79	5.87
50. G. G. (male)	12.1	Yes	4.33	8.6

CONCLUSION

The above results indicate that Ipana removes mouth odors of local origin in 22 subjects 4 hours after brushing and in 13 subjects 9 hours after brushing out of a total of 50 subjects.

After 4 hours, all odor threshold numbers were below 8.6. After 9 hours, all odor threshold numbers were below the original ones, and only 7 were 8.6 or above.

Respectfully submitted.

Dr. LOUIS C. BARAIL.

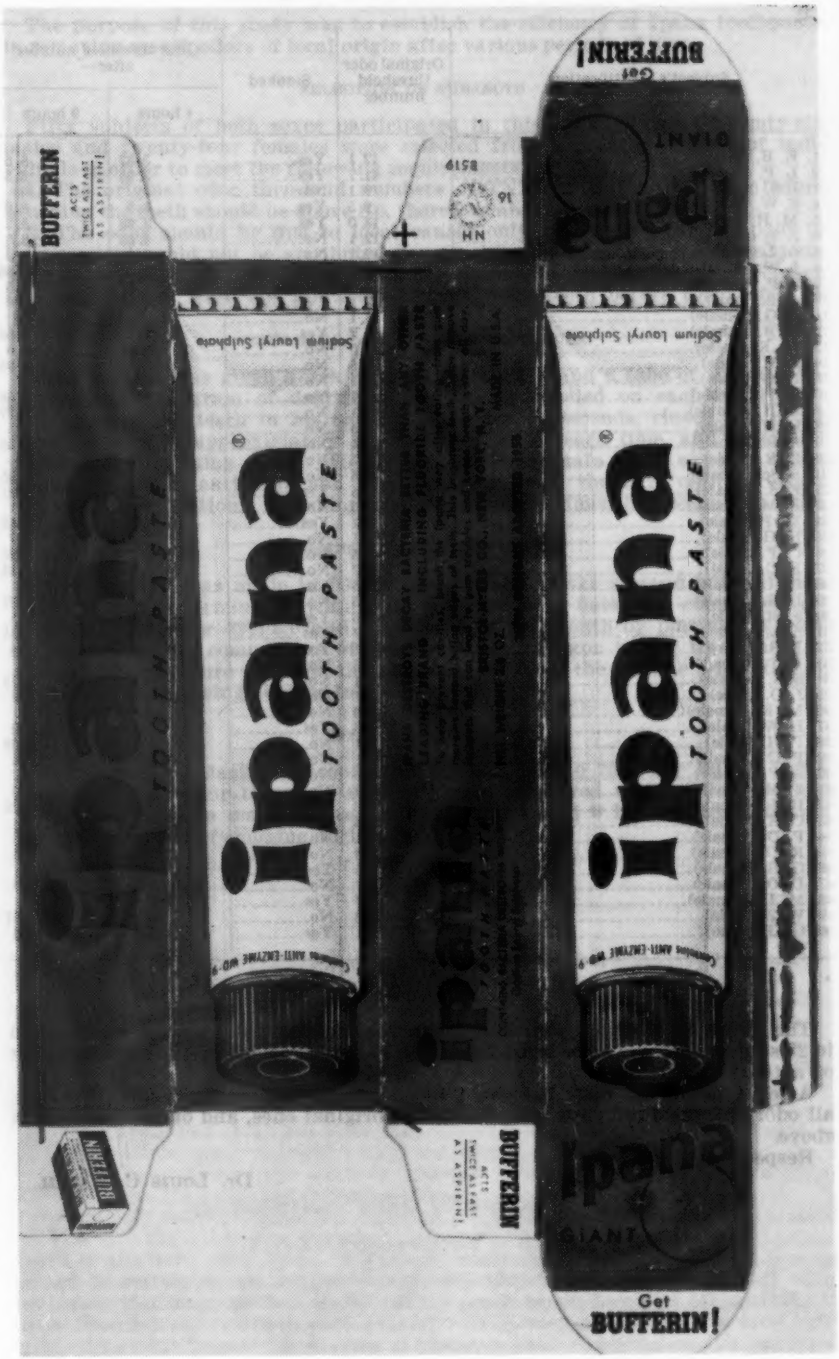

ipana
TOOTH PASTE
Sodium Lauryl Sulphate
BUFFERIN
Get
BUFFERIN!
GIANT

EXHIBIT 4

GOOD HOUSEKEEPING,
New York, N. Y., August 13, 1958.

Mr. JEROME S. PLAPINGER, Esq.,
House of Representatives Legal and Monetary Affairs Subcommittee of the Committee on Government Operations, Washington, D. C.

DEAR MR. PLAPINGER: Your letter of July 21, 1958, forwarded a request from the Honorable William E. Minshall which reads substantially as follows: "I think it would be wise if this committee made a request of the Good Housekeeping people to state just upon what basis they make available that seal * * *." Immediately after our response of July 24, we learned that the committee had discontinued its hearings, at least temporarily. In the event the hearings are resumed, we feel Mr. Minshall and the committee will want to have available a complete reply to the request made, and that reply we are pleased to make herewith.

Good Housekeeping is a women's service magazine, having a monthly circulation of more than 4 million copies, and is a publication of the Hearst Corp., Hearst magazines division. The magazine is unique in that it maintains at the above address extensive laboratories and investigation facilities, staffed by technicians qualified to investigate products in numerous categories and to determine whether they are good and satisfactory products. In this connection, the magazine publishes on page 6 of each and every issue a statement which reads as follows:

"If any product or any service is not as advertised herein, it will upon request and verification of the complaint, be replaced or the money paid therefor refunded.

"Good Housekeeping has satisfied itself that all products and services advertised in this issue of the magazine are good products or services. Advertising claims accepted for certain products presuppose proper installation and/or servicing. Neither the manufacturer nor Good Housekeeping can be responsible for such work by dealers or independent contractors."

This guaranty has been in effect for more than 50 years.

Products submitted to Good Housekeeping for advertising must be found acceptable by and through the use of the technicians and laboratories outlined above. Products not found acceptable are ineligible for advertising in Good Housekeeping. (As a matter of magazine policy, certain classifications of products are not considered by Good Housekeeping on any basis whatever; i. e., hair dyes containing paraphenylenediamine; depilatories; alcoholic beverages, including wines and beer; cigarettes and tobacco.) Products that are found acceptable by appropriate members of the technical staff may be advertised in the magazine if the claims made for them are true and honest and accurate claims, allowances being made for decently reasonably puffery.

Good Housekeeping's laboratories, always open to the public, are the most extensive of their kind in the world of publishing. They include an engineering department, temperature control rooms, a textile laboratory, a beauty clinic, a chemistry laboratory, a food department (including 11 kitchens), a children's center, a home appliance laboratory, including laundries, and a home cleaning center.

Good Housekeeping tests thoroughly products ranging in character from vacuum cleaners and refrigerators and clothing, to facial creams and detergents and canned foods; from baby carriages and toys and carpets, to hair sprays and steam and electric irons and raincoats; from linens and ranges and washing machines and breakfast cereals, to sewing machines and paints and silverware. In some instances, particularly in the realm of cosmetics and health, consultation is had with foremost pediatricians, general practitioners, and dermatologists. Staff members of the magazine maintain in addition a regular and cordial and confidential mutually satisfactory relationship with all technical and research and experimental organizations, including the Food and Drug Administration and the American Medical Association in Chicago.

In the rare instances when products are considered satisfactory but have claims based on clinical research sponsored by manufacturers, the products are not accepted for advertising until the research is made available to us and found acceptable. (Such research may be carried on over a period of months, sometimes years, and almost invariably under the supervision of physicians and scientists in universities and private practice whose skill and reputations are unquestioned.)

In the dentifrice field, numerous dentifrices were found acceptable to Good Housekeeping but the chlorophyl and ammoniated claims made for them were not, and the advertising therefor was rejected.

Only three dentifrices have been accepted for advertising in Good Housekeeping in recent years. One of them is Crest, manufactured by Procter & Gamble. Crest toothpaste was first introduced in test markets in the spring of 1955. Immediately Good Housekeeping, as is its normal procedure with any consumer products likely to be offered to the general public, assembled such clinical data as was then available. The data seemed promising. For further information Good Housekeeping communicated, by mail, with Dr. Thomas Hill of the American Dental Association. Dr. Hill advised us that the clinical work, conducted at the University of Indiana, seemed encouraging and that the product appeared to have merit. Subsequent reviewing and editing of advertising copy submitted to us took into account all existing data. Good Housekeeping accepted as factual and correct the statements appearing in the advertising published in Good Housekeeping magazine. Attached hereto are representative copies of the advertisements which have so appeared. Good Housekeeping's guaranty applied to those advertisements, and would so apply today.

Another dentifrice accepted by Good Housekeeping is Colgate dental cream, manufactured by the Colgate-Palmolive Co. In 1953, when this product was offered to Good Housekeeping for advertising, Good Housekeeping knew already that the advertising copy was based upon the original Fosdick study, which clearly demonstrated a significant reduction in dental caries when the teeth were brushed promptly after each meal and between meal snacks. Colgate ribbon dental cream was the dentifrice used in the Fosdick study. It was understood that comparable results could be expected with any well formulated dentifrice. Subsequent studies by Dr. Fosdick confirmed the accuracy of the statements accepted by Good Housekeeping. A representative copy of the advertising appearing in Good Housekeeping is attached hereto.

The other dentifrice accepted for advertising in Good Housekeeping is Ipana, a product of the Bristol Myers Co. The claims for this product were not accepted until clinical data was made available to the magazine in support thereof. Our technicians were completely satisfied with the results of the data supplied and considered the claims made in the magazine truthful and in accord with the facts. As with the preceding dentifrices, the Good Housekeeping consumers' guaranty has always applied.

Every dentifrice is submitted to a complete chemical analysis in our chemical laboratory. One of the more important aspects of such analysis stems from examination of the abrasive material. The actual sizes of the particles of the abrasive are measured microscopically in order to make certain that they are not sharp or overly large. The abrasive material is also subjected to a special procedure which indicates whether or not it will produce scratching on a glass slide. We do not accept for advertising dentifrices which produce scratching under the conditions of this test, as this conceivably would mean that tooth enamel might be damaged. The standard test used by Good Housekeeping was developed during World War II as one of the criteria on which dentifrices were accepted or rejected for the Armed Forces.

All three dentifrices advertised in Good Housekeeping have been subjected in detail to the procedure referred to above, and were found completely satisfactory in every respect.

Once a dentifrice has been passed by our chemical laboratory, samples of it are distributed to consumers for actual use tests. A copy of the questionnaire accompanying these dentifrices is attached.

Attached to this letter are various additional exhibits which may be of interest to members of the committee. We believe that all of them are self-explanatory. In conclusion I should like to invite any and all members of your committee, or designated representatives thereof, to visit our laboratories and to meet the staff that conducts them. All of us are exceedingly proud of the work in behalf of the American consumer that has been done by Good Housekeeping over a long period of years. We are more than proud of the trust that the consuming public has in the integrity of our publication, its staff, and in its advertisers. All of this has been made possible through the Good Housekeeping consumers' guaranty and its symbol of that integrity—the Good Housekeeping guaranty seal.

If we can be of further assistance to your committee in presenting our story of our activities, we shall be delighted to cooperate in any and every way.

Sincerely,

HERBERT R. MAYES.

Product_____
Date due_____

DENTIFRICE QUESTIONNAIRE

Please use this product faithfully according to directions for _____ weeks. Then answer this questionnaire and return to Mrs. Jamason in the beauty clinic.

1. Do you usually use a tooth powder _____ or a tooth paste _____?
What brand? _____

2. When do you brush your teeth? Before breakfast _____ After breakfast _____ At bed time _____ Any other time _____

3. Do you like the consistency and texture of this dentifrice? Yes ___ No ___
If no, please explain:

Too thick_____
Too thin_____
Too dry_____
Too foamy_____
Not enough foam_____

4. Do you like the flavor of this dentifrice? Yes ____ No ____
5. Does this dentifrice seem to clean your teeth thoroughly? Yes ____ No ____
6. Do you like the after effect in your mouth? Yes ____ No ____
7. Do you feel it helps to sweeten the breath? Yes ____ No ____
8. Does this product, as far as you can tell, remove film from the teeth? Yes ____ No ____
9. Do you find that this dentifrice polishes the teeth and leaves them sparkling? Yes ____ No ____
10. How does this sample compare with your regular dentifrice? Better ____ Equal ____ Not as good ____
11. In your opinion, is this a satisfactory product? Yes ____ No ____
If not, please explain: _____

Comments:
Name _____
Extension _____

EXHIBIT 5

ANALYSIS OF FEDERAL TRADE COMMISSION ACT, SECTION 12 (a) AND SECTION 15 (a) (1)

(Submitted by Hon. John W. Gwynne, Chairman, Federal Trade Commission)

I. Section 12 (a) makes unlawful the dissemination of any false advertising for the purpose of inducing, or which is likely to induce, the purchase of foods, drugs, devices, or cosmetics.

II. Section 15 (a) (1) lays down certain rules by which the term "false advertisement" is to be interpreted. It includes:

(1) Any advertisement which is misleading in a material respect, because of:

(a) Representation made.

(Example: A false statement that a certain dentifrice will prevent cavities.)

(b) Representations suggested by statement, word, design, device, sound, or any combination thereof.

(Example: A picture of dentists' office, etc., which suggests that a dentifrice has some quality in connection with dental hygiene which it does not in fact have.)

The section then enumerates certain failures to disclose information which might amount to false advertising. They are:

(*a*) Failure to reveal certain material facts which might be thought not to exist because of the representations made.

(Example: A commodity might be advertised as effective in the cure of a certain ailment, whereas the truth is that it is effective in only certain types of cases. The failure to set out clearly in the advertisement these limitations render the advertisement false.)

(*b*) Failure to reveal material facts with respect to consequences which might result from use of the commodity:

(1) Under conditions prescribed in the advertisement; or

(2) Under such conditions as are customary or usual.

(Example: A dentifrice might be advertised as effective in the whitening of teeth but the advertisement might fail to reveal the fact that its use might damage the teeth. Such failure might render the advertisement false.)

In other words, this section is purely interpretive. The law requires that counsel supporting the complaint must prove:

(1) That certain statements have been made or suggested;

(2) That such statements or suggestions are false; counsel supporting the complaint must prove—

(1) That even though the statement is literally true, it fails to reveal facts that, in effect, make it untrue; or

(2) That even though the advertisement correctly states what the commodity will do, it fails to state certain consequences which will follow the use of the commodity.

There is nothing in section 15 (a) (1) which indicates that Congress meant to shift the burden of proof from counsel supporting the complaint to the respondent. Such an interpretation, being contrary to the general philosophy of the common law as enforced in criminal statutes, Government regulations, and civil litigation, would not be adopted by the courts unless Congress has clearly so ordered it.

EXHIBIT 6

COLGATE-PALMOLIVE CO.,
New York, December 9, 1957.

Hon. JOHN A. BLATNIK,
Chairman, Legal and Monetary Affairs Subcommittee,
House Office Building, Washington D. C.

DEAR SIR: In further reference to your letter of October 31 we are submitting herewith copies of the magazine and newspaper advertisements, and also the radio and television commercials, used for Colgate dental cream and Brisk toothpaste during the 12 months prior to November 1, 1957. We have, however, eliminated duplications of any advertisement resulting from mere differences in size, format, illustration, or color.

We might point out that much of the present-day knowledge of the causes and mechanism of tooth decay is the result of research during and since World War II. In the 1940's there was increasing recognition of the theory that the formation of acids, as a result of enzymatic action on carbohydrates, is an important cause of tooth decay. No clinical proof was available that tooth decay could be reduced by brushing the teeth immediately after eating, but it was believed that if sweets and certain other foodstuffs play a part in the decay process, their removal from the mouth as soon as possible would reduce the number of new cavities.

At that time the Colgate-Palmolive Co. had been supporting research at the Northwestern University Dental School, and in 1947 the company supplied funds to Northwestern for a large-scale clinical test, to be continued for 2 years, on the effect of brushing the teeth right after eating. This test, in which students at 5 universities participated, showed that tooth decay was reduced about 50 percent among the students who brushed their teeth immediately after eating, as compared with those who brushed according to their usual habits. The enclosed reprint from the Journal of the American Dental Association, February 1950, contains a report on this test.

As we realized that many persons could not or would not consistently brush their teeth promptly after eating, we undertook, prior to completion of the above test, to develop a toothpaste with one or more ingredients which would remain active in the mouth for several hours, thereby inhibiting acid formation when carbohydrates were introduced. Some aspects of this research are described in the booklet entitled "Facts About Colgate Dental Research" and the reprint from the Journal of Dental Research, August 1953, copies of which are enclosed. The use of sodium N-lauroyl sarcosinate (Gardol) in both Colgate dental cream and Brisk toothpaste stems from this work.

Clinical tests of a toothpaste containing Gardol have shown reductions of about 50 percent in new cavities, as compared with a similar dentifrice without this ingredient. We are enclosing reprints from the Northwestern University Bulletin, Autumn 1953, and from Science magazine, June 1, 1956, covering the clinical study with 2,543 subjects, of whom 1,159 completed the full 2 years of the test. Similar results have been obtained in a recent clinical test with 365 schoolchildren, but the report has not yet been published.

We appreciate the opportunity you have given us to furnish this material.

Sincerely,

H. W. REYNOLDS,
Vice President and General Counsel.

[From Science, June 1, 1956, vol. 123, No. 3205]

CLINICAL EXPERIMENT ON THE USE OF SODIUM N–LAUROYL SARCOSINATE IN THE CONTROL OF DENTAL CARIES

The belief is widely held that dental caries is caused by acids formed on a tooth surface by the enzymic degradation of carbohydrates.[1] On the basis of this concept, attempts have been made to control dental caries by reducing the availability of the sugar substrate,[2] by making the tooth more resistant to acids [3] or by the prevention of fermentation. One method of control that has been suggested [4] makes use of enzyme inhibitors to prevent the glycolysis of the sugars. This method has been clinically tested with the use of a dentifrice containing 2-percent sodium N-lauroyl sarcosinate,[5] a very effective inhibitor of hexokinase *in vitro* [6].

The test subjects were young adults from the Meredith Publishing Company, Des Moines, Iowa, and from the student bodies of the University of Miami, Florida, the University of Florida, Gainesville, and Drake University. The experiment at each geographic location was conducted independently by different investigators, although the procedures used were the same and were formulated by an overall coordinator.

Each subject was classified in one of the following test groups. *T–1–D:* Subjects used a dentifrice containing 2 percent sodium N-lauroyl sarcosinate morning and night. *T–2–D:* The same dentifrice was used after each meal. *C–1:* Subjects used a dentifrice of their choice in the manner to which they were accustomed. *C–1–D:* Subjects used, morning and night, a dentifrice identical to that used by the T–1–D and T–2–D groups, except that sodium N-lauroyl sarcosinate was replaced by 2 percent sodium salt of sulfated glyceride of coconut fatty acids. In all groups except C–1, instructions were given for proper brushing techniques, and all subjects were issued dentifrice and brushes as needed.

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[1] K. A. Easlick, Dental Caries: Mechanism and Present Control Techniques (Mosby, St. Louis, Mo., 1948).
[2] P. Jay, J. Am. Dental Assoc. 27, 393 (1940); L. S. Fosdick, ibid., 40, 133 (1950).
[3] H. T. Dean et al., Public Health Repts. U. S. 56, 761 (1941); J. C. Muhler et al., J. Dental Research 33, 606 (1954).
[4] L. S. Fosdick et al., J. Dental Research 32, 486 (1953).
[5] This work was done under a grant from the Colgate-Palmolive Company, and this paper is the result of a cooperative effort on the part of the following members of the faculty of Northwestern University Dental School: R. R. Fosket, C. W. Freeman, P. C. Salisbury, L. W. Tibbits, B. F. Anderson, S. L. Carr, D. N. Fowler, F. G. Lauder, F. C. Jefferies, O. G. McKenzie, and D. Morrison, Jr.
[6] J. A. Carbon et al., Arch Biochem. 55, 356 (1955).

TABLE 1.—*Dental caries activity during 2-year test period*

Group	Installation	Condition at start				2-year increment of dental caries			
		Number of subjects	Average age	Average number DMF surfaces	Average number DF teeth	Teeth $\bar{x}$	Teeth σ^2	Surfaces $\bar{x}$	Surfaces σ^2
C-2-D	Gainesville	41	20.2	51.6	19.7	0.76	0.49	7.51	14.55
	Miami	86	22.1	39.4	16.6	.57	.51	3.19	4.91
	Meredith	182	26.6	35.8	16.0	.39	.40	1.78	2.72
	Drake	74	18.8	34.1	16.2	.38	.43	1.69	3.04
	All groups	383	23.4	38.0	16.6	.47	.45	2.69	7.63
T-1-D	Gainesville	60	19.5	44.5	19.0	.40	.45	4.25	9.62
	Miami	107	21.5	37.3	16.0	.18	.25	1.12	2.09
	Meredith	116	26.7	37.1	16.3	.15	.16	.68	.95
	Drake	135	19.5	34.6	16.0	.21	.26	1.07	1.79
	All groups	418	22.0	37.4	16.5	.22	.26	1.43	4.10
T-2-D	Gainesville	36	20.3	55.9	20.1	.50	1.00	4.22	15.22
	Miami	105	23.0	40.2	16.2	.24	.25	1.20	1.78
	Both groups	141	22.3	44.2	17.2	.31	.44	1.97	6.90
C-1	Gainesville	19	19.7	56.5	20.5	.79	1.62	7.00	24.00
	Miami	82	22.1	34.6	15.4	.62	.83	2.71	5.48
	Meredith	86	26.6	35.0	16.1	.44	.48	1.92	3.18
	Drake	30	19.4	32.0	15.2	.17	.14	1.40	3.35
	All groups	217	23.3	36.4	16.1	.50	.68	2.60	7.82

TABLE 2.—*Comparison of control and test results*

Contrast	Installation	Teeth Reduction (percent)	Teeth t	Surfaces Reduction (percent)	Surfaces t
C-2-D versus T-1-D	Gainesville	47	[1] 2.62	43	[2] 4.72
	Miami	68	[3] 4.45	65	[2] 7.82
	Meredith	62	[2] 3.67	62	[2] 6.55
	Drake	45	[1] 2.07	37	[3] 2.88
	All groups	53	[2] 5.88	47	[2] 7.40
C-2-D versus T-2-D	Gainesville	34	1.34	44	[3] 3.73
	Miami	58	[2] 3.76	62	[2] 7.65
	Both groups	51	[3] 3.83	57	[2] 7.03
C-1 versus T-1-D	Gainesville	49	1.74	39	[3] 2.90
	Miami	71	[3] 4.22	59	[3] 5.75
	Meredith	66	[3] 3.78	65	[2] 6.33
	Drake	−24	−.40	24	1.14
	All groups	56	[2] 5.33	45	[2] 6.02
C-1 versus T-2-D	Gainesville	37	.92	40	[1] 2.30
	Miami	61	[3] 3.64	56	[3] 5.55
	Both groups	52	[3] 3.23	44	[3] 3.98

[1] Significant level 0.05.
[2] Significant level 0.001.
[3] Significant level 0.01.

Since it was expected that 30 to 40 percent of the participants in the experiment would drop out each year, the homogeneity of the groups was not determined until the experiment had been completed. Comparisons were made then from data collected before the tests among the various groups and locations in respect to distribution of age; sex; DMF (decayed, missing, filled) surfaces; DF teeth; missing teeth; caries-free surfaces; caries-free teeth; free proximal surfaces; free labial, lingual, or buccal surfaces; and free occlusal surfaces.

At the start of the experiment, the average age of the subjects was 26 at Meredith, 19 at Drake, 22 at Miami, and 20 at Gainesville. In all groups and locations, the males were slightly more numerous than the females. Although within each group the numbers of decayed, missing, and filled surfaces were consistent, the counts were somewhat higher at Meredith and considerably higher at Gainesville. Initial examinations were made on 2,543 subjects. At the end of the first year of the test, there were 1,883. This number decreased to 1,159 subjects who completed the full 2 years of the experiment.

The increment of new carious surfaces was determined by clinical examination and radiographs, as was the involvement of teeth that had been noncarious at the start of the tests. In this regard, test subjects were compared with the controls with the data from each installation. Inasmuch as the group at Gainesville was not strictly comparable with the others on the basis of oral conditions at the start of the experiment, the distribution between the test and control subjects was such that it was thought of interest to list each group separately in addition to indicating overall results.

The results of the 2-year experiment are shown in tables 1 and 2 and indicate that sodium N-lauroyl sarcosinate in a dentifrice, when it is used either morning and night or after meals, will materially reduce dental caries activity. The percentage reductions in table 2 are average reductions for the test groups. Individual subjects may have derived more or less benefit than the average. The results from each group, with the exception of a small group at Drake and one at Gainesville, are highly significant, whether the comparisons are made on the basis of teeth involved or tooth surfaces involved.

L. S. FOSDICK,
Northwestern University Dental School, Chicago, Ill.

NOVEMBER 16, 1955.

A NEW APPROACH TO THE PROBLEM OF DENTAL CARIES CONTROL

L. S. FOSDICK, J. C. CALANDRA, R. Q. BLACKWELL, AND J. H. BURRILL

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IT IS generally believed by most research workers that dental caries is caused by acids formed as a result of the action of microorganisms on carbohydrates. The process is characterized by a decalcification of the inorganic portion of the tooth and is accompanied by or followed by a disintegration of the organic matrix.[1] Theoretical considerations and some experimental data indicate that all of the carbohydrate that may be converted to acids for the production of dental caries is derived from the diet.[2] Furthermore, the only portion of the diet that may be effective in the caries process is that which is available on the tooth surface after the food is ingested. The acids are formed on the tooth surface, and, if they are not neutralized by the saliva or otherwise destroyed, the decalcification of the tooth will proceed.

On this basis it is obvious that in order to control dental caries one must prevent the acid from forming, produce conditions under which the acids will be destroyed before harm results, or make the tooth itself more resistant to the action of the acids. All of the methods that have been successful so far in the restriction of dental caries have conformed to one or more of these fundamental concepts. For example, the use of fluorides[3, 4, 5, 7, 8, 9] and soluble oxalates[6] have been shown either to make the tooth more resistant to acids or to have actually restricted dental caries. The elimination of fermentable carbohydrate from the diet[10-16] and increasing the natural neutralizing influences of the mouth have been partially successful in the restriction of dental caries.

In 1942 it was suggested that, in order to be effective in the control of dental caries, brushing of the teeth should be done immediately after eating. If the carbohydrates rapidly ferment on the tooth surface after the ingestion of sugars, it is clear that most of the damage from any particular ingestion is complete within a short interval of time. Thus, if the mouth were to be cleansed thoroughly immediately after the ingestion of the harmful ingredients, one should be able to eat sugars and still not be subject to dental caries. In 1942[17] a limited laboratory experiment indicated that caries could be controlled by oral hygiene procedures, but it was not until 1949[18] that a clinical investigation was carried out. The results of this experiment showed conclusively that dental caries was materially reduced by simply cleaning the mouth immediately after eating. The same effect has been produced in animals by not permitting the sugar to come in contact with the teeth.[19] Thus, when caries-active rats are given cariogenic diets by stomach tube, no carious lesions can develop.

From theoretical aspects of the problem, one of the most effective ways of preventing dental caries would be by the use of enzyme inhibitors. In so far as

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the acids which attack the tooth surface are derived from sugars by enzyme action, one should be able to block the formation of acid by the use of compounds that would inactivate the enzymes concerned. Such compounds as vitamin K, urea, ammonia, and a host of others are known to interrupt the chain of reactions which are necessary for the production of acids. In fact, there are literally hundreds of compounds of this nature which might be classified as enzyme inhibitors or antienzymes. The main difficulty involved, however, is a practical and effective method of application. It is obvious that, in order for the glycolytic reactions to be inhibited, the enzyme inhibitors must be present at the time the fermentable carbohydrate is present. This means that the inhibitor may be incorporated into the sugar that is ingested; it could be placed in the mouth immediately before, after, or during the consumption of sugar; or it may be fastened to the tooth surface in some manner so that it will be present when sugars are ingested. A compound suitable for incorporation in the sugar at the refinery would be highly desirable, but to date no such compound has been reported in the literature.

The introduction of enzyme inhibitors shortly before or after the ingestion of carbohydrates presents the same general problems as are entailed with the dietary control of dental caries and oral hygiene procedures. It necessitates a change in the usual habits of the individual, and, unless individuals can be interested sufficiently, the mass control of dental caries by these methods never will become popular.

On an experimental basis it was found that when vitamin K was placed into a chewing gum and used immediately after the ingestion of food there was an appreciable decrease in caries activity. It was found further that when calcium carbonate was placed into a chewing gum so that acids could be neutralized more readily there was also a decrease in caries activity. The main difficulties with this procedure were that it involved a change in the habits of the individual and, even though the procedure may control dental caries, it is not practical.

Ammonia, urea, and copper chlorophyllin have been incorporated into dentifrices on the basis that these ingredients would inhibit the fermentation of acids from carbohydrates. Only a 10 per cent decrease in caries activity was noted by the use of ammonia and urea.[20] There is no published clinical evidence that dentifrices containing the copper chlorophyllin are effective in reducing caries activity. These compounds are not retained on plaque material for an appreciable period of time[21] and are rapidly cleared from the mouth. Hence, they should not be particularly effective as enzyme inhibitors in this situation unless they can be placed in the mouth with each ingestion of sugar. Thus, some mechanism whereby the enzyme inhibitors may be retained on the tooth surface for longer periods of time is a prerequisite to the successful application of this method.

It has been noted by many investigators that the carious lesion always occurs under what is commonly called the dental or mucinous plaque. The dental plaque is consistently present on the unclean surfaces of the teeth. It is difficult to remove and by the usual oral hygiene procedures can be cleaned only

from those surfaces accessible to the toothbrush. It has been suggested many times that caries could be controlled if the dental plaque could be prevented from accumulating on the tooth surface, or if the dental plaque could be removed completely by means of oral hygiene procedures.

An investigation into the chemical composition and the physical and chemical characteristics of the plaque indicate that it is protein in nature[22-24] and is probably a natural protection against acid foods. It consists primarily of living and dead organisms and denatured salivary proteins. After it is completely removed it is rapidly redeposited so that, even though caries probably could be prevented by the elimination of the plaque, so far it has been impossible to keep the tooth free from plaque or even to prevent its formation. It is a source of most of the enzymes involved in the carious process and it serves as a sponge to hold the sugars and acids in contact with the tooth surface.

In 1949[25] it was suggested that if the dental plaque could not be eliminated or modified so as to be harmless it might serve as an agent for the retention of enzyme inhibitors on the tooth surface. The plaque is protein in nature and it is known that various stains will attach themselves to protein. This being the case, one might borrow the concept of chemotherapy from Ehrlich and incorporate an enzyme inhibitor into the molecule of a substance that would attach itself to the plaque. If compounds could be found that would absorb, adsorb, or otherwise attach themselves to the plaque, and at the same time be powerful enzyme inhibitors either in situ or by being gradually released from the plaque, these compounds could be incorporated into an effective therapeutic mouthwash or dentifrice.

Certain characteristics of the compound are desirable. In the first place, it must be effective in the prevention of acid formation from sugar, and it must attach itself to the plaque and should remain active for a period of several hours. It should be relatively nontoxic and it should be colorless. Furthermore, it should not be unpleasant to the taste and it should be readily available. With this concept in mind, screening technics were devised whereby the inhibition of acid formation and absorption onto the plaque surface could be determined. For the inhibition of acid formation the technics previously published were used, wherein the rate of acid formation in saliva-enamel-sugar mixtures was determined both with and without the inhibitor.[26-28] For the absorption or attachment onto the dental plaque the method of Fosdick, Ludwick, and Schantz was used,[21] or in some cases inhibitors were preliminarily screened by adsorption on casein. The casein then was rinsed well with water and placed in Snyder's medium with caries-active saliva.[29]

When it became apparent that compounds could be found that would become attached to dental plaques and remain after washing with water, it was of interest to determine whether or not the compounds would remain effective in the mouth. For this purpose the following technic was employed. Patients were selected from the student body and from those applying to the dental clinic for treatment. The pH of the plaque material from the proximal surfaces of noncarious teeth was measured according to the method of Campaigne.[30] The

mouth then was rinsed for thirty seconds with a 50 per cent sucrose solution, after which more plaque was removed from the same surface at five-minute intervals for twenty minutes, and the pH of each sample was measured. If, during the twenty-minute period, the acidity of the area was equivalent to a pH of 5.2 or below, the individual was considered suitable for the screening technic. It was found that only 33 per cent of the individuals had readily accessible areas of the teeth that satisfied this requirement.

When subjects were found that had readily available proximal tooth surfaces that consistently attained a pH value of 5.2 after the application of the sugar solution, they were issued a dentifrice or mouthwash containing an "active ingredient." They were instructed to either rinse their mouths or brush their teeth in the morning upon arising and in the evening before retiring for a period of seven days. On the seventh morning they returned to the laboratory for the sugar rinse. They were permitted to have breakfast, but they were not permitted to brush their teeth or to clean their mouths on the morning of the test.

The pH of the plaque material then was taken, after which the mouth was rinsed with a 50 per cent sugar solution and the acidity of the plaque was measured at five-minute intervals for twenty minutes as previously described. If the plaques did not attain an acid potential of 5.5 or below during the twenty-minute interval, the therapeutic agent was considered worthy of further study. Thus, if unmedicated plaques consistently formed acid to a potential of pH 5.2 or below when sugar was applied, and consistently did not attain a potential of pH 5.5 or below after one week of medication, the therapeutic was considered effective in regard to the inhibition of acid formation on the tooth surface. To date three compounds have been found to be effective in this manner, two of which are stable in water solution and in a dentifrice. Seven others show promise but have not been subjected to use in vivo.

RESULTS

Investigation of several hundred compounds indicated that, although most antiseptics, many aldehydes, ketones and anionic and cationic detergents, and other types of compounds, would prevent the formation of acid in sugar-saliva mixtures, very few would become attached to the plaque and remain active after washing with water.

The results of the screening test in regard to the inhibition of acid formation in sugar-saliva mixtures are shown in Table I. It should be noted that almost one-half of the compounds tested inhibited acid formation in a concentration of 50 mg. per 100 c.c. Furthermore, most of the antibiotics and antiseptics were effective in much smaller concentrations.

In contrast to the phenomenon of the inhibition of acid formation, of all the compounds tested, only penicillin, aureomycin, terramycin, subtilin, some amino acid derivatives of 5-nitrofuroic acid, sodium N-lauroyl sarcosinate,*

*The sodium N-lauroyl sarcosinate was synthesized in the Colgate-Palmolive-Peet laboratories and was found to be effective in the casein adsorption test. The adsorption on dental plaque was confirmed in this laboratory.

TABLE I
ACID INHIBITION IN SALIVA

A. COMPOUNDS EFFECTIVE AT 5 MG. PER 100 ML.

Acid acetone yeast extract, alkyldimethylbenzylammonium chloride, alkyldimethylethylbenzylammonium chloride, 4-amino-isophthalic acid, aureomycin, bacitracin, 1-(1-benzyl)-dodecylbenzyldimethylammonium chloride, bis-2-chloro-1,4-naphthoquinonyl-3-p-aminoazobenzene, calcium monofluorophosphate, cetyldimethylethylammonium bromide, cetyltrimethylammonium bromide, N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-N'-2-pyridylsulfanilamide, N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)'-N-(2-pryrinidyl)-sulfanilamide, 2-chloro-3-(2,4-dimethylphenylamino)-1,4-naphthoquinone, 2-chloro-(3,4-dimethyl-2-pyridylamino)-1,4-naphthoquinone, 2-chloro-3-(β-hydroxyethylamino)-1,4-naphthoquinone, 2-chloro-3-(5-methyl-2-pyridylamino)-1,4-naphthoquinone, 2-chloro-3-morpholino-1,4-naphthoquinone, chloromycetin, 2-chloro-1,4-naphthoquinone, coco-dimethylamine · HCl, 2,6-di-(2-chloro-1,4-naphthoquinonyl)-aminopyridine, dihydrostreptomycin, N-dodecyl-β-alanine, dodecylaminolactate-dodecylamine-salicylate complex, n-heptylchlororesorcinol, (2-α-hydroxybenzyl)-1-dodecylbenzylammonium chloride, (2-α-hydroxybenzyl)-1-dodecylcinnamyldimethylammonium chloride, lauryldimethylamine · HCl, laurylisoquinolinium bromide, laurylphenylethyldimethylamine bromide, laurylphenylmethyldimethylamine chloride, 2,2'-methylenebis-(4-chlorophenol), 2,2'-methylenebis-(3,4,6-trichlorophenol), methylene blue, N-methyl-N-(5-nitrofuroyl)-p-aminophenol, N-methyl-N-(5-nitrofuroyl)-aniline, morpholinium ethyl sulfate, morpholinium soya ethyl sulfate, 5-nitrofuroic acid, N-(5-nitrofuroyl)-diethylamine, N-(5-nitrofuroyl)-ethanolamine, N-(5-nitrofuroyl)-phenylethanolamine, penicillin G, 1-(phenyl-1-decyl)-cinnamyldimethylammonium chloride, 1-phenyldodecylbenzyldimethylammonium chloride, 1-phenyldodecyldimethylcinnamylammonium chloride, soya trimethylammonium chloride, streptomycin, subtilin, 2-sulfanilamido-5-amyl-5-thiazolone, terramycin, p-tertiary-octylphenoxyethoxyethyldimethylbenzylammonium chloride, Zephiran chloride.

B. COMPOUNDS EFFECTIVE AT 10 MG. PER 100 ML.

Aceto-n-heptylresorcinol, 5-amino-5-methyl-1,3-bis-(2-ethylhexyl)-hexahydropyrimidine, aminopropyl tallow amine, cetyldimethylamine · HCl, cetyldimethylbenzylammonium chloride, N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-N'-guanylsulfanilamide, N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-N'-2-thiazolylsulfanilamide, 2-chloro-3-diisopropylamino-1,4-naphthoquinone, 2-chloro-3-(2-pyridylamino)-1,4-naphthoquinone, decylamine · HCl, di-n-butylresorcinol, dicaprylamine · HCl, dodecylamine lactate, dodecylamine undecylenate, formaldehyde, heptaldehyde, n-heptylresorcinol, hexadecylamine · HCl, n-hexylchlororesorcinol, lauryldimethylbenzylammonium chloride, myristyldimethylamine · HCl, 5-nitrofuramide, 5-nitrofuroylamide, N-(5-nitrofuroyl)-2-amino-3-methylpyridine, N-(5-nitrofuroyl)-6-amino-2-methylpyridine, N-(5-nitrofuroyl)-aniline, 5-nitrofuroylglylglycine, N-(5-nitrofuroyl)-2-methyl-6-aminopyridine, N-(5-nitrofuroyl)-morpholine, N-(5-nitrofuroyl)-p-nitroaniline, octadecenyldimethylethylammonium bromide, octadecyldimethylbenzylammonium chloride, octylamine pectin, n-octyl chlororesorcinol, sodium N-myristoylsarcosinate, N-stearoylalanine, N-stearoylmorpholine, 2-sulfanilamido-4-methyl-5-chloropyrimidine, tallo amine · HCl, tetradecylamine · HCl, tyrothricin.

C. COMPOUNDS EFFECTIVE AT 25 MG. PER 100 ML.

Acetaldehyde, N-(acylcolaminoformyl)-methylpyridine chloride, 4-aminomethylbenzenesulfonamide · HCl, Armeen CD, cetyldimethylbenzylammoniumchlorobenzomercapto thiazole, cetyldimethylethylammonium chloride, 1-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-guanadine, hemicarbonate, Congo red, 2,3-dichloro-1,4-naphthoquinone, dodecylamine, ethyl-N-5-nitrofuroyl-aminocaproate, glutamic acid, 3-hydroxy-2-methylpyridine-1,4-naphthoquinone, isobutyraldehyde, 5-nitrofuroylaminobutanol, N-(5-nitrofuroyl)-2-amino-1-butanol, N-(5-nitrofuroyl)-2-amino-4-methylpyridine, N-(5-nitrofuroyl)-2-amino-5-methylpyridine, 5-nitrofuroylglycine, 5-nitrofuroyl-o-toluidine, octadecyldimethylethylammonium chloride, polymyxin, propionyl resorcinol, sodium N-lauroylsarcosinate, N-stearoylglutamic acid.

D. COMPOUNDS EFFECTIVE AT 50 MG. PER 100 ML.

N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-N'-(4-methyl-2-pyrimidyl)-sulfanilamide, N4-(3-chloro-1,4-dihydro-1,4-dioxo-2-naphthyl)-N'-sulfanilamide, 2-chloro-3-di-n-propylamino-1,4-naphthoquinone, 2-chloro-3-(3-methyl-2-pyridylamino)-1,4-naphthoquinone, N-(2-chloro-3-1,4-naphthoquinonyl)-glycine, N-(2-chloro-3-1,4-naphthoquinonyl)-lysine, dibenzylacetone, dimethylaniline picrate, enterogastrone, ethyl-N-(5-nitrofuroyl)-glycinate, gramicidin, 2-hendecynoic acid, 9-hendecynoic acid, isopropyl benzoate, laurylphenylpropyldimethylamine bromide, methyl-p-hydroxybenzoate, 2-methyl-3-hydroxy-1, 4-naphthoquinone, 2-methyl-1,4-naphthoquinone, α-naphthol-picrate, p-nitrobenzyl maleate, N-(5-nitrofuroyl)-δ-aminocaproic acid, N-(5-nitrofuroryl)-2-aminopyridine, 5-nitrofuroyldimethylamine, N-(5-nitrofuroyl)-diphenylamine, N-(5-nitrofuroyl)-ethylamine, 5-nitrofuroylglycylalanine, 5-nitrofuroylglycylglutamic acid, 5-nitro-

furoylglycylleucine, N-(5-nitrofuroyl)-glycine, N-(5-nitrofuroyl)-methylamine, 5-nitrofuroylmorpholine, n-propyl-p-hydroxybenzoate, pyocyanine dihydrochloride, secondary C_{16} and C_{18} amine acetate, tech., secondary coco amine · HCl, sodium N-(o-chlorobenzoyl)-sarcosinate, sodium-N-cinnamoylsarcosinate, sodium dehydroacetate, sodium p-naphthoquinone-4-sulfonate, sodium N-palmitoylsarcosinate, N-stearoyl-ethanolamine, N-stearoylglycylglycine N-stearoylmethionine, 2-sulfanilamido-5,5-diethyl-4-thiazolone, 2-sulfanilamido-4-dimethyl-5-bromopyrimidine, 2,4,6-tribromo-m-cresol, 2,4,6-trimorpholinomethylphenol.

E. COMPOUNDS NOT EFFECTIVE AT 50 MG. PER 100 ML.

Acetoguanamine, p-acetylaminobenzenesulfonyl-DL-alanine, p-acetylaminobenzenesulfonyl-glycine, p-acetylaminobenzenesulfonylglycyl-DL-phenylalanine, p-acetylaminobenzenesulfonyl-DL-isoleucine, p-acetylaminobenzenesulfonyl-DL-leucine, p-acetylaminobenzenesulfonyl-L-(-)-leucine, p-acetylaminobenzenesulfonyl-DL-norleucine, p-acetylaminobenzenesulfonyl-DL-norvaline, p-acetylaminobenzenesulfonyl-DL-phenylalanine, p-acetylaminobenzenesulfonyl-DL-valine, acetyl urea, DL-alanine, alanine · HCl, D-alanylglycine, Alperox C (technical lauroyl peroxide), p-aminobenzenesulfonyl-DL-alanine · HCl, p-aminobenzenesulfonyl-DL-isoleucine · HCl, p-aminobenzenesulfonyl-DL-leucine · HCl, p-aminobenzenesulfonyl-DL-norleucine · HCl, p-aminobenzenesulfonyl-DL-norvaline · HCl, p-aminobenzenesulfonyl-DL-phenylalanine, p-aminobenzenesulfonyl-DL-valine · HCl, 4-amino-3-pentadecylphenol · HCl, D-arabinose, L-arabinose, Benzedrine sulfate, benzoguanamine, N-benzoylsarcosine, S-benzylcysteine, beta methylumbelliferone, 2-bromo-3-decylamino-1, 4-naphthoquinone, N-(5-bromofuroic)-p-toluidine, N-(5-bromofuroyl)-glycylalanine, N-(5-bromofuroyl)-morpholine, p-bromophenacylfuroate, butyl-p-hydroxybenzoate, calcium indoleacetate, carbobenzoxy-D-alanine, carbobenzoxy-D-alanyl chloride, carbobenzoxy chloride, carbobenzoxyglycine, carbobenzoxyglycyl chloride, carbobenzoxyglycylglutamic acid, carbobenzoxyglycylglycine, carbobenzoxyglycylglycylglycine, carbobenzoxy-L-tryptophan, carbobenzoxy-L-tryptophanyl chloride, chloroacetyl chloride, chloral phenylhydrazone, 2-chloro-3-(2-aminoamyl)-1,4-naphthoquinone, 2-chloro-3-(ω-aminocaproic acid)-1,4-naphthoquinone, 2-chloro-3-decylamino-1,4-naphthoquinone, 2-chloro-3-di-sec-butylamino-1,4-naphthoquinone, 2-chloro-3-isobutylamino-1,4-naphthoquinone, 2-chloro-3-isopropylamino-1,4-naphthoquinone, 2-chloromethyl-5-hydroxy-1,4-pyrone, 2-chloro-3-propylamino-1,4-naphthoquinone, 2-chloro-3-sec-butylamino-1,4-naphthoquinone, N-cinnamoyl sarcosine, citrinin, N,N-dibenzoylcystine, N,N-dicarbobenzoxycystine, diketopiperazine, N,N-diphenylacetylcystine, diphenylacetyl-DL-ornithine, 2,5-ditertiarybutyl quinone, ethanolamine, ethyl-alpha-aminoisobutyrate, ethyl-N-benzoylsarcosinate, ethyl glycinate, ethyl glycinate · HCl, ethylidene glucose, ethyl-5-nitrofuroate, ethyl sarcosinate, ethyl sarcosinate · HCl, ethyl-N-stearoylglycylglycinate, ethyl-N-stearoylsarcosinate, ethyl vanillate, ferrous sulfate, formoguanamine, fumaryl glycidic acid, furfurylsemicarbazone, N-furoylsarcosine (anhydrous), glucosamine, L-glucose, glucosozone, D-glyceric aldehyde, DL-glyceric aldehyde, glyceryl-N-α-naphthylcarbamate, glycine, glycine anhydride, glycine · HCl, glycyl-L-glutamic acid, p-glycylaminobenzenesulfonyl-DL-phenylalanine · HCl, glycyl-alpha-aminoisobutyric acid, p-glycylaniline, glycylglycine, guanidinium mercaptocethane sulfonate, 10-hendecynoic acid, histamine, p-hydroxybenzoylalanine, p-hydroxybenzoylmethionine, p-hydroxybenzoylphenylalanine, p-hydroxyhippuric acid, 3-hydroxy-2-(methylacetone)-1,4-naphthoquinone, inositol, isoleucine, isoleucine · HCl, isopropyl-n-phenylcarbamate, leucine, leucine · HCl, maleic anilide, mannuronic acid lactone, Marsilid phosphate, 3-mercapto-1-trimethylammonium bromide propane, 2-methoxy-1,4-naphthoquinone, methylaminoacetonitrile, 2-methyl-3-hydroxynaphthalene, 2-methyl-3-methylacetate-1,4-naphthoquinone, morpholine, N-(p-Nitrobenzoyl)-sarcosine, p-nitrobenzylacetyl salicylate, N-5-nitrofuroylalanyltyrosine, 5-nitrofuroylglycyllysine, 5-nitrofuroylglycylphenylalanine, 5-nitrofuroyl-m-nitroaniline, 5-nitrofuroyl-p-nitroanaline, N-(5-nitrofuroyl)-p-toluidine, N-(3-nitrophthalyl)-2-sarcosine, 2-nonone-3-hydroxy-1,4-naphthoquinone, norleucine, norleucine · HCl, norvaline, norvaline · HCl, Palatone, D-pantothenyl alcohol, phenacylacetylsalicylate, phenolphthalein, phenylacetyl-L-alanine, phenylacetyl-L-arginine, phenylacetyl-L-cystine, phenylacetylglycine, phenylacetylglycylvaline, phenylacetyl-L-lysine, phenylacetyltryptophan, D,L-phenylalanine, phenylalanine · HCl, picric acid, pontamine white dye, n-propoxy-2-amino-4-nitrobenzene, pyrogallol triacetate, salicylaldehyde semicarbazone, sodium benzoate, sodium N-benzoylsarcosinate, sodium bisulfite, sodium borate, sodium N-(p-chlorobenzoyl)-sarcosinate, sodium N-diphenylacetylsarcosinate, sodium N-(p-ethoxybenzoyl)-sarcosinate, sodium N-furoylsarcosinate, sodium p-hydroxybenzoylaspartate, sodium p-hydroxybenzoylglutamate, sodium p-hydroxybenzoylisoleucinate, sodium p-hydroxybenzoylnorleucinate, sodium p-hydroxybenzoyltryptophanate, sodium p-hydroxybenzoylvalinate, sodium N-(o-iodobenzoyl)-sarcosinate, sodium N-(p-nitrobenzoyl)-sarcosinate, sodium 3-nitrophthalylalaninate, sodium 3-nitrophthalylaspartate, sodium 3-nitrophthalyl-L-glutamate, sodium 3-nitrophthalylglycinate, sodium 3-nitrophthalyl-DL-isoleucinate, sodium 3-nitrophthalyl-DL-leucinate, sodium 3-nitrophthalylmethionate, sodium 3-nitrophthalylphenylalanate, sodium 3-nitrophthalylvalinate, sodium phthalylglycylglycinate, sodium N-stearoylsarcosinate, sodium N-(m-toluoyl) sarcosinate, sodium N-(o-toluoyl)-sarcosinate, sodium N-(p-toluoyl)-sarcosinate, N-stearoylalanyl hydrazide, N-stearoyl-δ-aminocaproic acid, N-stearoyl-δ-aminocaproic ester, N-stearoylglycine, N-stearoylglycyl hydrazide, N-stearoylsarcosine, N-

stearoyltaurine, 2-sulfanilamido-5-bromopyrimidine, 2-sulfanilamido-5-chloropyrimidine, 2-sulfanilamido-4,6-dimethyl-5-chloropyrimidine, 2-sulfanilamido-5,5-dimethylthiazolone, 2-sulfanilamido-5-ethyl-4-thiazolone, 2-sulfanilamido-4-methyl-5-bromopyridine, 2-sulfanilamido-4-thiazolone, tannic acid, taurine, threonine, N-(m-toluoyl)-sarcosine, N-(o-toluoyl)-sarcosine, N-(p-toluoyl)-sarcosine, L-tryptophanylglycine, tyrocidine, valine, valine . HCl, D-xylose, L-xylose.

sodium dehydroacetate,* sodium N-myristoyl sarcosinate, (1-phenyl-1-decyl)-cinnamyl-dimethyl-ammonium chloride and 1-phenyldodecyl-benzyl-dimethyl-ammonium chloride were retained effectively on the plaque after the washing period. It also should be noted that there seems to be no relation between the activity of the acid inhibitor and retention on the plaque.

It is obvious that before a therapeutic ingredient may be used in vivo on human beings it must be proved harmless to the individual. If it is to be used in a dentifrice or mouthwash it must be compatible with the type of preparation, it must be stable over relatively long periods of time, and it must be pleasing to the taste and sufficiently active so that it may be incorporated in reasonable quantities. Furthermore, it is quite probable that compounds widely used in medicine, such as many of the antibiotics, should not be used in a dentifrice or mouthwash, even though they may be effective in preventing dental caries. If the use of an antibiotic in a dentifrice reduced the effectiveness of the antibiotic in serious diseases, then its incorporation into dentifrices or mouthwashes would be contraindicated.

Of all of the compounds that were found to be effective in the prevention of acid formation, and that at the same time resisted removal from the plaque material, only two are known to fulfill all of the above requirements. Sodium N-lauroyl sarcosinate and sodium dehydroacetate are nontoxic, they are stable and can be incorporated effectively into a dentifrice or mouthwash, they prevent the acid formation in saliva-sugar mixtures, and they are retained effectively on plaque material. None of the derivatives of 5-nitrofuroic acid, nor any of the effective detergents other than sodium N-lauroyl sarcosinate, have been studied sufficiently in regard to toxicity for in vivo studies. All of the other compounds that satisfied the above requirements are antibiotics; however, many of these are unstable in aqueous solution. For this reason, at least for the present, only sodium N-lauroyl sarcosinate and sodium dehydroacetate were selected for in vivo testing in dentifrices or mouthwashes.

Inasmuch as penicillin has been investigated intensively in regard to the prevention of dental caries, and inasmuch as the sodium dehydroacetate and the sodium N-lauroyl sarcosinate behave very similarly to penicillin in regard to the prevention of acid formation in saliva mixtures and in regard to retention on plaque material, it was decided to include penicillin in a tooth powder as a reference material. It was found that, after seven days' use in a therapeutic dentifrice or mouthwash, all three of these compounds would prevent the tooth surface of individuals using the therapeutic from becoming more acid than pH 5.5. Fig. 1 shows the relative effectiveness of these compounds. As can be seen from this graph, the maximum acidity obtained after sucrose was the same

*The sodium dehydroacetate was shown initially to be effective for acid inhibitory activity and adsorption on plaque in vivo in the laboratories of the Lambert Pharmacal Company Division of the Lambert Company.

for all three compounds. Penicillin was tested on sixty individuals, sodium N-lauroyl sarcosinate was tested on 144 individuals, and sodium dehydroacetate was tested on 145 individuals.

In addition to the above, other tests were performed in order to determine whether or not continued use of the potentially therapeutic compounds would build up a tolerance, such as has been observed with penicillin.[33] Large scale clinical experiments were started wherein the subjects used the therapeutic products in the morning upon arising and in the evening before retiring. Adequate placebo and control groups also were included. Complete dental examinations, including radiographs, were made in order to determine the number of carious lesions present. It was intended that these experiments would continue for a period of two years, after which time the clinical efficacy could be determined.

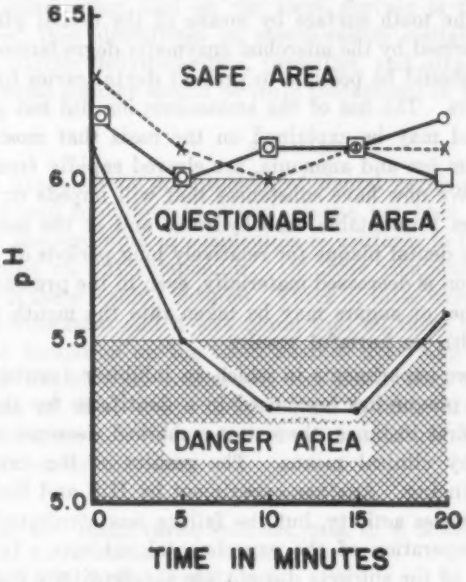

Fig. 1.—Average plaque pH after sucrose rinse.
• Control
□ Penicillin
O Sodium N-lauroyl sarcosinate
X Sodium dehydroacetate

At the end of a nine-month period, the acidity attained on the tooth surface after a 50 per cent sugar rinse was determined in the same manner as described in the seven-day test.

It was found (Table II) that 44 per cent, 95 per cent, and 89 per cent of the cases remained above pH 5.5 during the twenty-minute interval after the use of the placebo, sodium lauroyl sarcosinate, and sodium dehydroacetate, respectively. Thus, it would seem that both of the compounds remained active after the nine months' use.

TABLE II
ACID FORMATION ON THE TOOTH SURFACE AFTER NINE MONTHS' USE OF THERAPEUTIC DENTIFRICE

pH	PLACEBO		SODIUM LAUROYL SARCOSINATE		SODIUM DEHYDROACETATE	
	NUMBER	PER CENT	NUMBER	PER CENT	NUMBER	PER CENT
5.2 and below	65	56	4	5	6	11
5.3 to 5.5	99		9		4	
5.6 to 5.9	98	44	28	95	32	89
6.0 and above	30		215		50	
Totals	292		256		92	

DISCUSSION

If dental caries is initiated by a characteristic decalcification by acids held in close contact with the tooth surface by means of the dental plaque, and if the acids in turn are formed by the microbial enzymatic degradation of fermentable carbohydrates, it should be possible to prevent dental caries by the proper use of enzyme inhibitors. The use of the ammonium ion did not give entirely satisfactory results, and may be explained on the basis that most substances, including the ammonium ion and ammonia, are cleared rapidly from the mouth by the salivary flow. We now have substances that will impede or prevent the formation of acids from fermentable carbohydrates and at the same time will attach themselves to the dental plaque for relatively long periods of time. Thus, the rate of acid formation is decreased materially, even in the presence of sugars, for long periods of time, or sugars may be taken into the mouth at any time during this interval with no harmful results.

There have been two experiments in which an inhibitor (penicillin) that is retained by the dental plaque has been used in a dentifrice for the control of dental caries. In the first instance, there was a marked decrease in caries activity as determined by clinical means. The results of the experiment by Zander[31] are very convincing. Another experiment by Hill and Kniesner[32] reported no decrease in caries activity, but the failure was attributed to the difficulty in obtaining cooperation of the experimental subjects. It was shown conclusively that many of the subjects did not use the dentifrice consistently.

It is known that penicillin will prevent the formation of acids from sugar. It is known further that this substance will be retained on the dental plaque for from twelve to twenty-four hours. There is excellent evidence that the plaques in situ that contain the penicillin will resist changes in pH after the application of sugar, and there is excellent evidence that when a penicillin dentifrice is used consistently there is a marked decrease in caries activity. In view of this, it is quite logical that other substances that perform in the same manner should cause a material decrease in caries activity when used in a dentifrice or mouthwash.

To date about ten compounds have been found which will become attached to the plaque material in effective concentrations and resist washing with water.

Of these, three have been incorporated into dentifrices or mouthwashes and have been tested in vivo. In each case the results have been favorable. Two of these, sodium N-lauroyl sarcosinate and sodium dehydroacetate, are now under test clinically. After nine months of this clinical test, it was found that both compounds were still effective in blocking acid formation below what has been considered the harmful level. This dividing line is empirical and is based primarily on laboratory evidence. No accurate estimates concerning the effect of these compounds on clinical caries can be made, but it would be interesting to speculate on the possible results. If the dangerous acidity is pH 5.5 and the carious process is an all-or-none proposition, then there should be no appreciable differences in the caries-inhibiting action of the two compounds. However, if this is not the case, they might possibly develop a difference, as one of the compounds depressed the formation of acid to a greater extent.

If we assume that acid on the tooth surface is the immediate cause of dental caries, then dentifrices or mouthwashes containing sodium N-lauroyl sarcosinate, sodium dehydroacetate, penicillin, and other compounds which behave in the same manner should be truly therapeutic in the prevention of dental caries.

SUMMARY

A new approach to the problem of dental caries control based upon the retention of acid inhibitors in dental plaque has been suggested. Laboratory technics for the screening of compounds to conform to this theory were devised and performed on 381 compounds. Of these compounds, ten were found to be effective in the screening technics. Three of these were tested in vivo in dentifrices or mouthwashes and it was found that all three materially decreased the rate of acid formation on the tooth surface over long periods of time. Continued daily use of these compounds has shown that their efficiency is maintained. Two of these compounds, sodium N-lauroyl sarcosinate and sodium dehydroacetate, are now under clinical test to measure quantitatively their therapeutic effect on dental caries.

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THE REDUCTION OF THE INCIDENCE OF DENTAL CARIES. I. IMMEDIATE TOOTH-BRUSHING WITH A NEUTRAL DENTIFRICE

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It is now generally believed by most dental research investigators that dental caries is initiated by an acid decalcification of the enamel surface under an organic coating or dental plaque.[1] Contrary to earlier concepts, it is now definitely known that the acids are for the most part formed very rapidly from fermentable carbohydrates by means of a well defined series of reactions which in turn are governed to a large extent by enzyme systems.[2,3] Furthermore, it is known that in caries-active mouths the acids are formed extremely fast.[4,5] In many mouths free acid, in sufficient concentration to decalcify the tooth, may be present on the enamel surface within three minutes after the ingestion of the fermentable sugar, but in most cases the maximum acidity on the tooth surface is present within about 20 minutes after the ingestion of sugar[6] and may persist for from 30 to 90 minutes. Thus, the actual carious process is not ordinarily a

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long continuous process, but is an intermittent one, and consists of a series of short periods of decalcification, interspersed with periods in which no decalcification occurs but putrefaction may take place.

Concurrently with the formation of acid, there is a degree of defense against the acids in each mouth.[7] A large number of variables, many of which are present in most mouths, combine to render the acid harmless or to prevent its formation. The degree of protection in the population of so-called "civilized" countries is ordinarily not sufficient, so that most people suffer, to a greater or lesser degree, the ravages of dental caries. This is probably due to an increased rate of acid production in most cases, rather than to a decreased amount of protection. The reason is obvious in many instances, but there are still many factors that require further investigation.

On the basis of the above, whether or not all of the variables are thoroughly understood or known, there are several ways by which dental caries may be prevented. Many of these have been tried, either clinically or by means of laboratory experimentation, so is it now quite clear what must be done in order to prevent this important disease.[7] Since the acids are derived from fermentable sugar by enzymic action, it is obvious that by eliminating the sugars or by inactivating one or more of the enzymes, dental caries could be prevented. On the other hand, if the acids could be destroyed or rendered innocuous, either by neutralizing or otherwise removing them, or if the tooth could be rendered less soluble, caries could also be prevented. It has been shown beyond all reasonable doubt that the elimination of the substrate by dietary means is effective,[8, 9, 10] but only in cases where sugars are actually unavailable is this method generally successful. Numerous examples of enzyme inhibitors such as fluorides[11, 12, 13] Zephiran, [14] vitamin K,[15] ammonia[16] and urea,[17, 18] have been used experimentally with varying degrees of success. Rendering the tooth more resistant to acids (for instance by the use of fluorides,[11, 12, 13]) has also been successful. Thus it would seem that, from a practical and theoretical point of view, any method that performs any of the necessary functions of preventing the formation, or which rapidly neutralizes or destroys the acids, should prevent dental caries provided practical methods of application could be found.

One method of caries control that has been suggested frequently but has never adequately been tried experimentally[19] is that of simple oral hygiene procedures. If the maximum acid potential is reached about 20 minutes after the ingestion of sugars, a thorough cleansing of these substrates from the mouth, along with

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11. Knutson, J. W., and Armstrong, W. D., Effect of Topically Applied Sodium Fluoride on Dental Caries Experience: Report of Findings for Second Study Year., *Pub. Health Rep.* 60:1085 (Sept. 14) 1945.

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15. Burrill, D. Y., Calandra, J. C., Tilden, E. B., and Fosdick, L. S., Effect of 2-methyl-1, 4-naphthoquinone on the Incidence of Dental Caries. *J. D. Res.* 24:273, 1945.

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17. Stephan, R. M., Effect of Urea in Counteracting the Influence of Carbohydrates on the pH of Dental Plaques. *J. D. Res.* 22:63 (Feb.) 1943.

18. Wach, E. C., O'Donnell, J. F., and Hine, M. K., Effects of a Mouth Rinse on Oral Acidogenic Bacteria. *J.A.D.A.* 29:61 (Jan.) 1942.

19. Fosdick, L. S., Etiology and Control of Dental Caries. *J.A.D.A.* 29:2139 (Dec.) 1942.

any acids formed within this interval of time, should prevent the initiation and progress of a carious lesion. There are several recognized methods by which this could be accomplished. A water or antiseptic rinse could be employed. This procedure probably would not remove much of the occluded debris or plaque material but, since the fermentable sugars are water soluble, it could conceivably dissolve and flush from the mouth much of the acids and fermentable sugars. There is little information available regarding the effectiveness of a rinse of the above type in removing sugars or acids from the mouth.

Another possible method — and one that is in general use for cleansing the mouth—is brushing the teeth. Although this procedure, with a suitable dentifrice, has long been advocated as a measure of general oral hygiene and has been practiced for generations, there are no reliable statistics regarding its effect on dental caries or its efficacy in cleansing the mouth. It is generally considered a good practice for reasons other than caries prevention. The usual routine has been to brush the teeth in the morning on arising and just before retiring. Theoretically, if the tooth-brushing procedure is to be effective in the control of dental caries, it must be performed immediately after each ingestion of sugar-containing foods. During the past few years this practice has been advocated intensely by dentists and research workers familiar with the carious process.[1, 20]

Although it is generally conceded that, if all sugars and acids were to be cleansed from the mouth before decalcification could occur, the incidence of caries would be reduced, there is little information concerning the efficiency of brushing in cleansing the teeth. A recent investigation[21] indicates that about 80 per cent of the debris can be removed by this process, but whether it can be removed before the acids can form and attack the enamel is problematical. For this reason, a comprehensive clinical experiment was started to determine the effect of proper brushing of teeth.

A great deal has been written on the proper type of dentifrice for the most efficient cleansing of the teeth. Some individuals feel that an antiseptic dentifrice should offer advantages over a nonantiseptic dentifrice, others that an antiseptic offers no advantage. Still others feel that a neutral or slightly acid dentifrice has superior cleansing effects to those of an alkaline dentifrice. Some argue in favor of a powder and some in favor of a paste. Others say that any dentifrice is simply a pleasant adjunct to an otherwise unpleasant task, and that a dentifrice serves no other purpose. The preponderance of evidence, however, indicates that an abrasive substance is necessary for proper cleansing. Because of financial limitations, it was impossible to test all types of dentifrices. Since tooth pastes are more widely used than powders, it was decided to use paste only. In this experiment an essentially neutral paste, an alkaline paste, and an antiseptic paste were investigated. The neutral paste consisted of dicalcium phosphate as the abrasive; glycerol; gums; flavor; a sulfated glyceride of coconut oil fatty acids as the detergent, and water. The antiseptic paste was identical with the neutral paste except that it had an efficient acridine derivative antiseptic present, and the alkaline paste was the usual precipitated chalk, soap type paste. This paper deals with the neutral paste only. The results of the other groups will not be available until a later date.

Experimental Procedure

A total of 946 individuals comprising 423 controls and 523 test subjects com-

20. Dental Caries: Prevention & Control (pamphlet), Chicago, American Dental Association.

21. Ludwick, W. E. and Fosdick, L. S., The Ammonium Ion Concentration in Dental Plaques. *J. D. Res.* In publication.

pleted the experiment. They comprised groups of liberal arts students from Drake University, Simpson College, and Emory University; the dental students of the University of Louisville, Emory University and Northwestern University, and the medical students of the University of Louisville. The groups were similar as far as possible in regard to oral conditions, age and sex. The average age of the test group was 22.7 and of the control group 23.5 years. Although there was a preponderance of males in both groups, the ratio of males to females was comparable.

All of those in the experimental group were instructed individually to brush their teeth thoroughly within 10 minutes after each ingestion of food or sweets, and when brushing was impossible to rinse the mouth thoroughly with water. They were instructed to brush their teeth with an accepted technic and to rinse the dentifrice from the mouth immediately after brushing. They were instructed to report the approximate number of times the brushing technic was omitted per day and, if they did not follow the technic after at least two meals per day continuously they were dropped from the experiment. Toothbrushes and dentifrice were supplied to all experimental subjects. Brushes were of a good quality and a standard pattern with twelve separated tufts of nylon bristle in two rows with the ends of the tufts cut wedge-shape.

The persons in the control groups were not supplied with dentifrices or brushes and were instructed to continue with their customary oral hygiene habits. The oral hygiene habits of all subjects except those in one group were determined and recorded. If the individuals brushed their teeth immediately after the ingestion of food, they were dropped from the experiment. In general, however, the oral hygiene habits of the control group were about the same as those of the test subjects previous to the experiment. Most of them ordinarily brushed their teeth only on arising and before retiring rather than after the ingestion of food. Only in exceptional cases were the teeth brushed only once per day or not at all. In general, the customary habit was to rinse the mouth free from dentifrice after brushing the teeth.

At the beginning of the experiment the teeth of each subject, in both experimental and control groups, were carefully examined by means of a mouth mirror, explorers, dental floss, and air syringe. Full mouth view and crown view roentgenograms were made for each experimental and control subject, with the exception of those from Simpson College and Drake University for whom crown view roentgenograms only were made. The roentgenograms were carefully examined by the original investigator with the aid of a magnifying glass and illuminator. After the original investigator had examined the roentgenogram and recorded his findings, the films were forwarded to a central office where another examination was made. Each roentgenogram was examined independently by two individuals, one of whom examined each of the roentgenograms of the entire test and control subjects. In cases where the two did not agree, the discrepancies were discussed with the two examiners and a conclusion reached. In case agreement was impossible, the area was omitted from the experiment. In the case of two groups, with the original investigator's consent, the discrepancies were judged by the second examiner and a third party.

At the end of one year and at the end of two years, the entire procedure was repeated. One control group, particularly the medical students, and a number of individuals in both groups, missed the examination at the end of the first year. Thus, for these exceptions, the caries experience for the two-year interval only is known. A number of individuals who started the experiment were dropped before the end of the first year. This was particularly true in the liberal arts schools where the students discontinued their

Table 1.—Comparison of test and control groups

	Control group		Test group		% Decrease test vs. controls
	Number of cases	Average number of new carious surfaces	Number of cases	Average number of new carious surfaces	
1st yr. clinical	306	2.21	526	0.82	63
1st yr. x-ray	308	0.87	528	0.32	63
2nd yr. clinical	146	1.11	422	0.82	26
2nd yr. x-ray	150	0.53	424	0.25	53
2 yrs. clinical	273	2.53	429	1.49	41
2 yrs. x-ray	271	1.34	429	0.53	60

education, but a few left the experiment because of a dislike of the procedure or because of noncooperation. The results were assembled in a central location and distributed to the various investigators before final statistics were compiled.

At the beginning of the experiment, and at six-month intervals, lactobacillus acidophilus counts were made according to the technic of Hadley.[22] This procedure was performed either at the institution concerned or, in the case of two groups, in the Iowa State Public Health Department. In one institution the acidophilus counts were discontinued after one year.

22. Hadley, Faith P., and Bunting, R. W., Further Studies on the Recognition of B. Acidophilus. *J.A.D.A.* 19:98 (Jan.) 1932.

Table 2.—Calculations for statistical tests of significance of differences between test and control groups

		Variance	Degrees of freedom	F	Probability of occurrence by chance alone
1st year clinical:	within groups	2.5797	830	144.95	less than .001
	among groups	373.9353	1		
1st year x-ray:	within groups	0.7757	834	76.77	less than .001
	among groups	59.5526	1		
2nd year clinical:	within groups	1.6441	566	5.537	between .01 and .05
	among groups	9.1026	1		
2nd year x-ray:	within groups	0.4710	572	17.70	less than .001
	among groups	8.3373	1		
2 years clinical:	within groups	3.7702	700	47.92	less than .001
	among groups	180.6643	1		
2 years x-ray:	within groups	1.3180	698	83.50	less than .001
	among groups	110.0564	1		

Table 3.—Calculations for statistical tests of significance of differences between test group and results of other studies

	Our test group						
	Number of cases	Average number of new carious surfaces	Estimated standard error of average	Other study	Average	t	Probability of occurrence by chance alone
1st year clinical..	526	0.82	.05264	U.S.M.A.	2.2	−26.30	less than .001
				U.S.P.H.S.	1.5	−13.00	less than .001
				D & H	1.75	−17.75	less than .001
2nd year clinical..	422	0.82	.12526	U.S.M.A.	2.2	−11.02	less than .001
				U.S.P.H.S.	1.5	− 5.43	less than .001
				D & H	1.75	− 7.43	less than .001
2 years clinical...	429	1.49	.08235	U.S.M.A.	4.4	−35.29	less than .001
				U.S.P.H.S.	3.0	−18.29	less than .001
				D & H	3.5	−24.36	less than .001
1st year x-ray....	528	0.32	.2830	Previous N.W.	1.2	−31.09	less than .001
2nd year x-ray...	424	0.25	.02794	Previous N.W.	1.2	−33.92	less than .001
2 years x-ray.....	429	0.53	.04321	Previous N.W.	2.4	−43.29	less than .001

Results

The results were compiled on the basis of new carious surfaces that developed the first year, the second year and the sum of the two years. In all cases the results were compiled on the basis of (1) clinical examinations with the use of roentgenograms, and (2) roentgenographic evidence only. The latter is probably the only objective type of examination possible in this type of experiment. Although the DMF surfaces involved were recorded for the purpose of determining the similarity of the groups, they are not herein reported as this experiment is primarily concerned with the present caries activity rather than the total lesions present. The distribution of individuals according to the number of new carious surfaces in each experimental period was also recorded in the results. The results of the test group were then compared with those of the control group and with those of other similar groups studied previously. These results were then subjected to a statistical analysis.

At the end of the experiment, it was found that the individuals in the test group had a statistically significant lower incidence of dental caries than those in the control group. This was true whether the comparison was made on the basis of clinical or of roentgenographic evidence (Tables 1 and 2). When the results were compared with those of other investigators (Table 3, and Figs. 1 and 2) similar results were obtained, although in some cases a greater difference was observed. A further analysis concerning the distribution of the cavities (Table 4, Figs. 3, 4, 5, 6) indicates a general trend. Subjects with slight caries activity developed no cavities while the more caries active became less active.

The first year controls yielded results

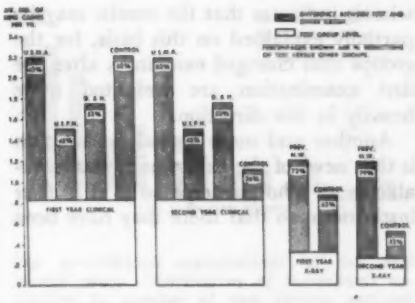

Fig. 1.—Comparison of average number of new carious surfaces developed per year, for test and control groups and other studies. First and second year results

identical with those found in students in the U. S. Coast Guard Academy[23] (2.2 new carious surfaces per year). This is slightly higher than the results of Hollander and Dunning, compiled from a study of 12,000 individuals in the Metropolitan New York area, wherein there was found an increment of 1.75 new carious surfaces per person in the similar age group. This was also higher than the U. S. Public Health Service statistics on similar age groups wherein there was found an increment of 1.5 cavities per year. The clinical results of the first-year group indicated an increase in carious surfaces of 0.8 cavities per person. This is a reduction of caries activity of 63 per cent when compared with the control group included in this experiment. The results are identical when compared with the individuals of the U. S. Military Academy. When the results are compared with the U. S. Public Health Service statistics[24] and those of individuals in the vicinity of New York City,[25] there is a reduction of 45 per cent and 53 per cent respectively.

Objective roentgenographic evidence on the first year study shows a 63 per cent reduction in caries activity compared with the controls. Unfortunately, there are few similar experiments recorded in the literature. The only other group with which to compare the roentgenographic evidence is that of previous students at Northwestern University.[18] Compared with this data, there is a reduction in caries activity of 73 per cent.

The results of the second year of the experiment show less reduction in caries activity than those of the first year. The average results of the test subjects are approximately the same in the first and second year of the experiment clinically and roentgenographically. The control subjects, however, showed less caries activity than they did the first year. Since

23. Arnold, F. A. Jr., Dean, H. T., and Singleton, D. E. Jr., Effect on Caries Incidence of a Single Topical Application of a Fluoride Solution to the Teeth of Young Adult Males of a Military Population. *J. D. Res.* 23:155 (June) 1944.

24. Private Communication.

25. Hollander, F., and Dunning, J. M., A Study by Age and Sex of the Incidence of Dental Caries in Over 12,000 Persons. *J. D. Res.* 18:43 (Feb.) 1939.

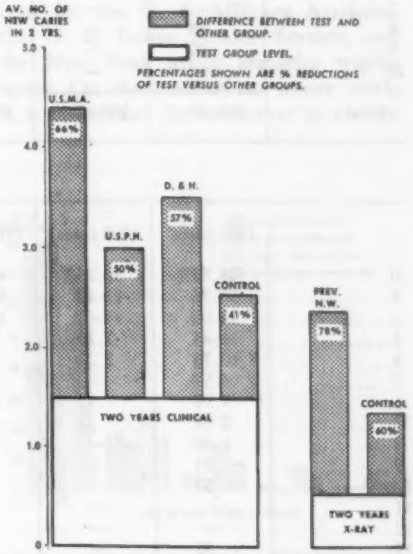

Fig. 2.—Comparison of average number of new carious surfaces in two years, for test and control groups and other studies

the control groups used no prophylactic measures, it is to be expected that the first and second years of the experiment should be fairly similar. The reason for this discrepancy is not clear, but two logical explanations could be offered. The error involved in the clinical examination may explain part of the differences. A breakdown of the data from the various schools indicates that the results may be partially explained on this basis, for the groups that changed examiners after the first examination are weighted quite heavily in this direction.

Another and more logical explanation is that news of the experiment was available to all who participated in it in four institutions, so that there may have been

Table 4.—Distribution of individuals according to number of new carious surfaces developed

Number of caries	Test group					
	1st year		2nd year		2 years	
	Clinical	X-ray	Clinical	X-ray	Clinical	X-ray
	(526 cases)	(528 cases)	(422 cases)	(424 cases)	(429 cases)	(429 cases)
0	55.70%	75.95%	57.58%	79.95%	35.20%	65.50%
1	21.86	17.99	19.43	16.04	25.64	22.61
2	13.50	4.54	12.09	3.30	17.72	7.46
3	5.90	1.14	7.11	.47	10.02	2.80
4	2.28	.38	2.84	—	6.29	1.16
5	—	—	.47	.24	2.10	.47
6	.19	—	.24	—	.93	—
7	—	—	—	—	.70	—
8	.38	—	.24	—	.70	—
9	.19	—	—	—	.47	—
10	—	—	—	—	.23	—
Total	100.00	100.00	100.00	100.00	100.00	100.00
	Control group					
	(306 cases)	(308 cases)	(146 cases)	(150 cases)	(273 cases)	(271 cases)
0	23.53%	53.25%	45.89%	68.67%	18.68%	38.74%
1	20.26	21.43	26.03	17.33	20.51	22.88
2	21.90	14.61	13.70	8.67	19.05	19.19
3	11.44	7.79	8.22	3.33	15.02	8.49
4	10.78	2.27	2.05	2.00	9.52	7.38
5	4.57	—	1.37	—	5.86	1.84
6	1.96	.33	2.05	—	3.30	1.48
7	2.61	.32	—	—	4.76	—
8	1.96	—	.69	—	2.56	—
9	.33	—	—	—	—	—
10	.33	—	—	—	—	—
11	—	—	—	—	.37	—
12	—	—	—	—	—	—
13	.33	—	—	—	.37	—
Total	100.00	100.00	100.00	100.00	100.00	100.00

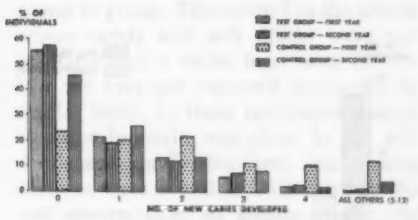

Fig. 3.—Clinical examinations for first and second years. Distribution of individuals according to number of new carious surfaces developed

a tendency for better hygiene practices in these control groups. In fact, in one institution a large percentage of the controls had to be dropped because they had changed their habits and were brushing their teeth immediately after the ingestion of sweets. Furthermore, during the time the experiment was under way, much publicity and interest on the part of the dental profession, as a result of the health education activities of the Council on Dental Health, encouraged people in general to use oral hygiene procedures immediately after eating. If this was the case, the reduction should be reflected in the roentgenographic study. The roentgenographic study does indicate a reduction in caries in the second year of examination. In any event, when the results of the test subjects are compared on a clinical basis with our own control groups and with the other available groups, it is found that there was a reduction in caries activity of 26 per cent. When compared with the statistics from the U. S. Military Academy, there is a 63 per cent reduction and when compared with the U. S. Public Health Service study and the one on individuals in the New York area, there are a 45 per cent and 53 per cent reduction respectively. The roentgenographic evidence indicates a reduction of 53 per cent when compared to our own controls and a reduction of 65 per cent when compared with the previous students of Northwestern University.

Unfortunately, since there has been no similar two years' study on the incidence of dental caries, it is impossible to compare the data of the two years' study with other groups without projecting the data of the previous one-year studies to two years. According to the data obtained by Hollander and Dunning on 12,000 individuals in the vicinity of New York City, the annual increase in carious surfaces does not change appreciably between the ages of 17 and 34. These investigators found that the annual increment of new carious surfaces was 1.75. If this data is correct, then the subjects from the U. S. Military Academy would develop 4.4 cavities, and those studied by the U. S. Public Health Service 3.0 cavities, in the two-year period, whereas those in the vicinity of New York City would develop 3.5 new carious surfaces in two years. On this basis, a comparison with the two years' study would indicate a reduction of 63 per cent, 45 and 53 per cent for the U. S. Military Academy, the U. S. Public Health Service, and the New York group statistics respectively. On the basis of the above work, it is plain that the reduction in carious

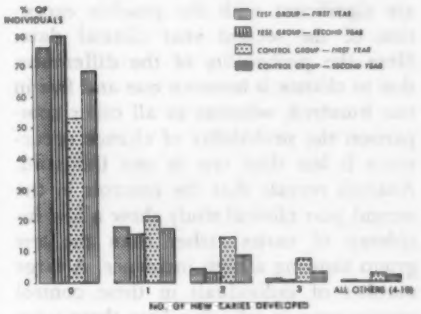

Fig. 4.—Roentgenographic examination for first and second years. Distribution of individuals according to number of new carious surfaces

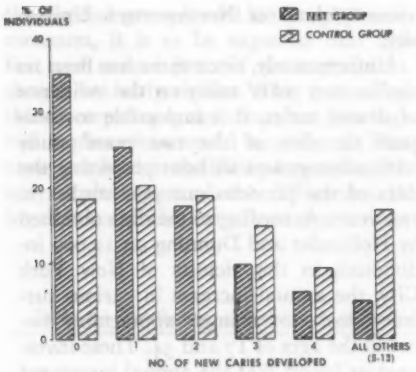

Fig. 5.—Clinical examination for total two years. Distribution of individuals according to the number of new carious surfaces developed

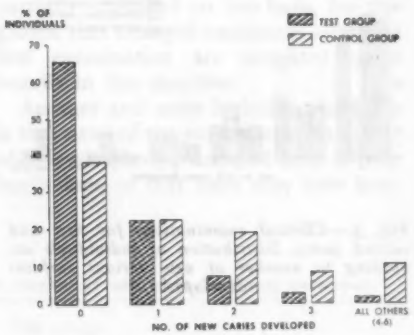

Fig. 6.—Roentgenographic examinations for total two years. Distribution of individuals according to numbers of new carious surfaces

activity by purely oral hygiene procedures is real and that the actual reduction is probably in the neighborhood of between 50 and 60 per cent.

Discussion

In any experiment of this type there are many factors that may alter results. Every effort was made to minimize these factors and at completion the data was subjected to rigorous statistical analysis. The evidence indicates that the values are significant with the possible exception of the second year clinical data. Here the probability of the differences due to chance is between one and five in one hundred, whereas in all other comparison the probability of chance occurrence is less than one in one thousand. Analysis reveals that the controls in the second year clinical study show a low incidence of caries rather than the test group showing a high incidence. A large number of individuals in these control groups were in schools where there were also individuals in a test group, and a number were dental students. Although it is definitely known that these control individuals did not use the after-meals brushing technics, it is felt by the primary investigators observing them that, during the second year, they unconsciously used better hygiene technics and rinsed the mouth after eating. When the results of the test groups are compared with the data from other sources, the degree of caries reduction remains high and is statistically significant.

One striking result of the brushing technic is the large numbers of individuals that developed only a few cavities during the one and two-year periods. Thus it seems that brushing the teeth immediately after eating will materially reduce the numbers of cavities, not in just the least susc ptible, but also in those cases where a multitude of cavities would otherwise develop. Those individuals who are only mildly caries-active develop no caries and the very active ones develop only a few lesions.

It should be recorded that in general all of the individuals in both the test and control groups had soft drinks and candy readily available during the day with the exception of one control group. This factor was reflected in the variations from

group to group. The control in the school where candy and soft drinks were not available had a caries increment far below the averages reported previously in similar work. In those institutions where a water fountain was close to the soft drink and candy dispenser, less carious surfaces were found in both control and test groups than in groups where the water was absent.

The above experiment indicates that the prevention of dental caries may be much simpler than has been generally thought. It is obvious that the toothbrush or the abrasive cannot physically reach the inner portions of the proximal areas. Hence it is to be expected that the forcible dilution of the material in these areas might account for the results. There is considerable evidence to substantiate this possibility.

In view of the favorable results reported above with the unmedicated dicalcium phosphate dentifrice, it is possible that the type of dentifrice and the type of abrasive are not important. However a positive statement to this effect must await the data on the other two groups; namely, the one in which soap and calcium carbonate was used, and the one in which detergent, dicalcium phosphate antiseptic was used.

Summary

A clinical test on the efficacy of brushing the teeth immediately after the ingestion of foods with a dicalcium phosphate detergent dentifrice, indicates that dental caries can be materially reduced by this method. The results indicate that by means of simple oral hygiene procedures dental caries activity can be reduced. The results are in accord with the generally accepted theory of the carious process and materially strengthen this theory.—*311 East Chicago Avenue.*

A Preliminary Clinical Report on the Effectiveness of Sodium N-Lauroyl Sarcosinate in the Control of Dental Caries†

By L. S. FOSDICK

This paper is the result of a cooperative effort on the part of the following members of the faculty of Northwestern University Dental School: R. R. Fosket, Chairman of the Department of Radiology; C. W. Freeman, Professor of Oral Surgery; P. C. Salisbury, Professor of Oral Surgery; L. W. Tibbitts, Instructor in Radiology; B. F. Anderson, Instructor; S. L. Carr, Instructor; D. N. Fowler, Instructor; F. G. Lauder, Instructor; F. C. Jefferies, Research Associate and Director of the Project at Drake University and the Meredith Publishing Company; O. G. McKenzie, Research Associate and Director of the Project at the University of Miami and the Jackson Memorial Hospital; and D. G. Morrison, Jr., Research Associate and Director of the Project at the University of Florida.

We also wish to express our appreciation to Doctors C. L. Craig, G. J. Coleman and R. T. Hill for assisting in the Miami Project and we wish to thank the administrative officials at the above-mentioned institutions for their hearty cooperation.

IN A previous report some new concepts concerning the etiology and control of dental caries were discussed.[1] It was shown that although there are many enzyme inhibitors available that would effectively block the formation of acid from fermentable sugars, none could be effective in a dentifrice or mouth wash unless some mechanism were evolved whereby these inhibitors could be held in the mouth on the tooth surface for a prolonged period of time. It was suggested that if the dental plaques, under which dental caries develops, could not be effectively removed, they might serve as the agent for the retention of enzyme inhibitors on the tooth surface. Insofar as the plaque is protein in nature it should be possible to find enzyme inhibitors that would absorb, adsorb, or otherwise attach themselves to the protein.

In subsequent reports[2,3] methods for screening compounds were described, and the results of a large-scale screening program were presented. Among the first of the compounds found effective by the screening techniques was sodium N-lauroyl sarcosinate. This compound, because of its desirable characteristics, was thought to possess sufficient merit to be used in a clinical experiment. If the results were found satisfactory, not only would a simple, practical method of caries control be made available, but the modern concept of the etiology of dental caries would be strengthened.

It was the original plan to continue the clinical experiment for two years before the results were announced. However, since the publication of the laboratory results of the screening program, so much confusion has arisen, both in the dental profession and among the consuming public, that it was thought expedient to publish a preliminary report of the first year of the two-year test. It was thought that if the results could be made available they would tend either to confirm or reject the theory and, if the theory were confirmed, to differentiate clearly between enzyme inhibitors that are absorbed, or retained on the plaque, and those that are not retained.

Experimental Procedure

The first year results were obtained from the radiographic records of 2,265 individuals. These were procured from the student bodies of Drake University, the University of Florida at Gainesville, Florida, the University of Miami, Florida, the Jackson Memorial Hospital in Miami, and the employees of the Meredith Publishing Company. This yielded a rather divergent geographic distribution.

Each project is under the immediate direction of a dentist in the community and the experiment has been carried out as much as possible by each independent investigator.

The experiment is being conducted in a manner similar to that in which it was found that cleansing the mouth immediately after the ingestion of food would reduce the incidence of dental caries.[4] The subjects are divided into groups. Two control groups are used. One, a random control, continues their oral hygiene procedures according to their established habits; they are furnished tooth brushes and use the dentifrice of their choice. No instructions are given concerning the fre-

quency of brushing, but information concerning the dentifrice used and the frequency of brushing is recorded.

The other control group is issued a placebo dentifrice and tooth brushes. They have been instructed to brush their teeth with an accepted technique in the morning upon arising and in the evening before retiring. The placebo dentifrice is composed of dicalcium phosphate, calcium carbonate, glycerol, gums and flavoring agent. In addition, the dentifrice contains 2% detergent which consists of the sulfated glycerides of coconut fatty acids, an excellent inhibitor of acid formation, but without the ability to attach to dental plaque or to be retained in the mouth.

There are also two test groups. Both test groups are furnished the same test dentifrice. This dentifrice has the same composition as the placebo dentifrice, except that the detergent is 2% in sodium N-lauroyl sarcosinate, an enzyme inhibitor which in the screening test was shown to become attached to the dental plaque and remain active on the tooth surface for from 12 to 24 hours. One group using the test dentifrice was instructed to brush their teeth on arising in the morning and in the evening before retiring in the same manner as those in the control group. The second test group, much smaller, was given the same instructions, except that they are to brush their teeth within ten minutes after eating, and if in a position where this is impossible, they are to rinse their mouths with water while still at the table.

At Drake University and the Meredith Publishing Company the first three groups are being used. At the University of Florida, Miami University and the Jackson Memorial Hospital, all four groups are used. The Jackson Memorial Hospital records are combined with those of Miami University.

At the beginning of the experiment each subject in each group was carefully examined for dental caries by means of mouth mirror, explorers, air syringe and light. The results were recorded on a card designed for the purpose. A special radiographic technique was used whereby two crown view exposures were made of each of the posterior teeth and regular root view exposures were made of the anterior teeth. Thus ten films were made at each examination.

This procedure was duplicated at the end of a complete year, during which time dentifrice and brushes were issued on request. A record of frequency of issue is kept and any individual who does not regularly obtain supplies is dropped from the test. It is planned to continue the test until all have completed two years.

The films were forwarded to a central office. Each film was examined independently by at least two examiners trained for the purpose. After the two independent readings were made and recorded, a third reading was made with the two independent examination records at hand and any discrepancies in the two recordings were oriented. The results were recorded as the number of new carious surfaces per person.

At the start of the experiment 3,400 individuals were examined, including 500 who underwent a one-year pre-test examination. At the end of the year 2,265 records were available. The rest had terminated their residence at the institution involved or were not considered suitable for the test because of over-age. No individual was used for the test who was over 35 years of age.

In general, it was observed that the cooperation has been good, but, as is usually the case, a number were dropped from the experiment for non-cooperation. The amount of dentifrice used by the subjects varied considerably from individual to individual. The following is a report of the results of the first year of the clinical test.

Results

The results were compiled for this preliminary report on the basis of radiographic evidence only, although clinical data were also available. It was thought that this evidence was the more objective of the two, but that both types of data should be made available for the final report. The data for each group in each institution were compiled separately and the totals combined. It was also thought of interest to combine the data for the two control groups and the two test groups, insofar as no significant differences existed between the two controls and the two test groups. Results were also compiled on the basis of the numbers of cavities developed. In each case a statistical analysis was made.

The results are shown in the following tables.

TABLE I. COMPARISON OF TEST AND CONTROL GROUPS

	Control Groups			*Test Groups*			Per Cent Decrease Test vs. Control
	Number of Cases	Average Age	Ave. No. Carious Surfaces	Number of Cases	Average Age	Ave. No. Carious Surfaces	
	Random			*Twice-a-Day Brushing*			
Gainesville	67	19	0.79	154	19	0.34	57%
Miami	123	22	0.71	161	22	0.24	66
Meredith	408	26	0.59	213	26	0.30	49
Drake	30	19	0.47	172	19	0.18	62
Total	628	24	0.63	700	22	0.27	57
	Random			*After-Meal Brushing*			
Gainesville	67	19	0.79	93	20	0.33	58
Miami	123	22	0.71	158	23	0.37	48
Meredith	408	26	0.59	—	—	—	—
Drake	30	19	0.47	—	—	—	—
Total	628	24	0.63	251	22	0.35	44
	Placebo			*Twice-a-Day Brushing*			
Gainesville	105	20	0.61	154	19	0.34	44
Miami	136	22	0.85	161	22	0.24	72
Meredith	294	23	0.67	213	26	0.30	55
Drake	151	19	0.76	172	19	0.18	76
Total	686	21	0.72	700	22	0.27	63
	Placebo			*After-Meal Brushing*			
Gainesville	105	20	0.61	93	20	0.33	46
Miami	136	22	0.85	158	23	0.37	56
Meredith	294	23	0.67	—	—	—	—
Drake	151	19	0.76	—	—	—	—
Total	686	21	0.72	251	22	0.35	51
	Total Control			*Total Test*			
Gainesville	172	20	0.68	247	20	0.34	50
Miami	259	22	0.78	319	22	0.30	62
Meredith	702	25	0.62	213	26	0.30	52
Drake	181	19	0.71	172	19	0.18	75
Total	1314	23	0.67	951	22	0.29	57
	Previous 1st Yr. Control[*]			*Total Twice-a-Day Brushing*			
	308	23	0.87	700	22	0.27	69
	Previous 1st Yr. Control[*]			*Total After-Meal Brushing*			
	308	23	0.87	251	22	0.35	60
	Previous 1st Yr. Control[*]			*Total Test*			
	308	23	0.87	951	22	0.29	67

[*] Fosdick, L. S., *J.A.D.A.*, 40:133, 1950.

TABLE II. CALCULATIONS FOR STATISTICAL SIGNIFICANCE

		Variance	Degrees of Freedom	F	Probability of Occurrence by Chance Alone
Random Control vs.					
Twice-a-Day Brushing	Within Groups	0.5619	1326	77.74	less than
Test Groups:	Among Groups	43.6829	1		.001
Placebo Control vs.					
Twice-a-Day Brushing	Within Groups	0.6793	1384	103.29	less than
Test Groups:	Among Groups	70.1682	1		.001
Random Control vs.					
After-Meal Brushing	Within Groups	0.6591	877	20.49	less than
Test Groups:	Among Groups	13.5025	1		.001
Placebo Control vs.					
After-Meal Brushing	Within Groups	0.8268	935	28.99	less than
Test Groups:	Among Groups	23.9697	1		.001
Total Control vs.	Within Groups	0.6726	2263	121.65	less than
Total Test Groups:	Among Groups	81.8224	1		.001
Random Control vs.	Within Groups	0.8568	1312	2.88	not
Placebo Control Groups:	Among Groups	2.4681	1		significant
Twice-a-Day Brushing vs.					
After-Meal Brushing	Within Groups	0.4152	949	3.51	not
Test Groups:	Among Groups	1.4591	1		significant
Previous 1st Year					
Controls* vs. Twice-a-Day	Within Groups	0.7004	1006	112.76	less than
Brushing Test Groups:	Among Groups	78.9793	1		.001
Previous 1st Year					
Controls* vs. After-Meal	Within Groups	0.9650	557	38.57	less than
Brushing Test Groups:	Among Groups	37.2224	1		.001
Previous 1st Year					
Controls* vs. Total	Within Groups	0.6520	1257	121.79	less than
Test Groups	Among Groups	79.4035	1		.001

*Fosdick, L. S., *J.A.D.A.*, 40:133, 1950.

It was found that the average number of cavities developed in the control groups varied slightly from institution to institution, the average on the random controls being .63 on 628 individuals. Those individuals using the placebo show an average of .72 on 686 individuals. Those that used the test dentifrice morning and night only showed an average of .27 new carious surfaces on 700 individuals, while those in the after-meal brushing showed an average of .35 new carious surfaces on 251 subjects. When the test and control groups were combined, the averages were .29 and .67, or a 57% reduction in new carious surfaces.

A statistical analysis was made of the results and it was found that, although some of the differences that existed in the small groups at each institution were not highly significant, when the total number of each group on the same procedure was used the probability of the differences' being due to chance was very remote.

It is of interest to note that none of the control groups showed a high caries incidence. Although this figure was low, it was in the same order of magnitude as was found in the control group of a similar experiment wherein the radiographic technique of analysis was similar.[4] Furthermore, the relative numbers of carious lesions in those that did develop dental caries were relatively the same. It was found that about 55% of the control cases developed no new cavities, while 78% of those that used the test dentifrice developed no new cavities. It should be emphasized, however, that this applies to proximal cavities only, as these are the ones that can readily be detected by radiographic techniques.

Discussion

On the basis of theoretical considerations and laboratory results, it was thought that sodium N-lauroyl sarcosinate, when incorporated into a dentifrice, should cause a reduction in the incidence of dental caries if the teeth were brushed morning and night as is the usual custom. It was further thought that a two-year test would give sufficient time to study the effects of this dentifrice. From previous experiments it was found that the results obtained during the first year were a fair criterion of effectiveness and that, although the first year may not yield conclusive proof, the results are not without merit. The results obtained conclusively show that on a one-year test sodium N-lauroyl sarcosinate in one dentifrice† will reduce caries activity. This is in accordance with the theory.

A very surprising result was that the immediate-brushing technique did not show any superiority over twice-a-day brushing. In fact, the raw data on the after-meal brushing were not as favorable as the twice-a-day brushing. We offer no

TABLE III. DISTRIBUTION OF INDIVIDUALS ACCORDING TO NUMBER OF NEW CARIOUS SURFACES DEVELOPED

Number of New Carious Surfaces	*Control Groups* Random 628 cases	Placebo 686 cases	Total 1,314 cases	*Test Groups* Twice-a-Day Brushing 700 cases	After-Meal Brushing 251 cases	Total 951 cases
0	55.89%	54.52%	55.17%*	80.43%	73.31%	78.55%*
1	29.94	27.70	28.77	14.86	19.92	16.19
2	11.14	12.39	11.80	3.29	5.18	3.79
3	1.75	2.92	2.36	0.71	1.19	0.84
4	0.96	2.19	1.60	0.57	0.40	0.53
5	0.32	0.14	0.23	0.14	—	0.10
6	—	0.14	0.07	—	—	—

*Difference is statistically significant to .001 level.

explanation of this except that the differences found were not statistically significant.

It should be noted that in one group, the Meredith Publishing Company, a number of older people approaching the age of 35 were used. This brought the average age of the control groups higher than the test groups. This should be of little importance, as it would, if anything, decrease the annual incidence of caries in the control group, and thus would make more conservative the results obtained.

It is realized that the age group used is not that of the greatest caries activity, but it is an age group wherein intelligent cooperation may be obtained. Furthermore, it is the same age group in which the immediate-brushing technique was used and with which these results may be compared.

It is quite obvious that there is a reduction in the annual increment of dental caries of about 60% when the teeth are brushed with the dentifrice containing sodium N-lauroyl sarcosinate. This is based on a one-year trial. The experiment is continuing for another year, at the end of which the experiment will be terminated and the results compiled. On the basis of previous experiments the results of the second year should be similar, unless a tolerance for the inhibitor develops.

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THE REDUCTION OF THE INCIDENCE OF DENTAL CARIES. I. IMMEDIATE TOOTH-BRUSHING WITH A NEUTRAL DENTIFRICE

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It is now generally believed by most dental research investigators that dental caries is initiated by an acid decalcification of the enamel surface under an organic coating or dental plaque.[1] Contrary to earlier concepts, it is now definitely known that the acids are for the most part formed very rapidly from fermentable carbohydrates by means of a well defined series of reactions which in turn are governed to a large extent by enzyme systems.[2,3] Furthermore, it is known that in caries-active mouths the acids are formed extremely fast.[4,5] In many mouths free acid, in sufficient concentration to decalcify the tooth, may be present on the enamel surface within three minutes after the ingestion of the fermentable sugar, but in most cases the maximum acidity on the tooth surface is present within about 20 minutes after the ingestion of sugar[6] and may persist for from 30 to 90 minutes. Thus, the actual carious process is not ordinarily a

This paper is the result of a cooperative effort on the part of the following investigators: A. P. Atkins, D.D.S., Research Associate, Northwestern University Dental School; D. Y. Burrill, D.D.S., M.S., Professor of Oral Diagnosis University of Louisville Dental School; J. H. Burrill., D.D.S., Assistant Professor of Oral Diagnosis, Northwestern University Dental School; R. R. Foster, D.D.S., Associate Professor of Radiology, Northwestern University Dental School; C. W. Freeman, D.D.S., M.S., Professor of Oral Surgery, Northwestern University Dental School; F. Garvin, D.D.S., Assistant in Research, Emory University Dental School; O. E. Hoffman, D.D.S., M.P.H., Director of Dental Health, Iowa State Health Department; F. C. Jefferies, D.D.S., M.S.D., Research Associate, Northwestern University Dental School; V. Johnson, D.D.S., Professor of Pedodontia, Emory University Dental School; W. Wolf, D.D.S., Assistant Professor of Oral Medicine, University of Louisville Dental School.

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long continuous process, but is an intermittent one, and consists of a series of short periods of decalcification, interspersed with periods in which no decalcification occurs but putrefaction may take place.

Concurrently with the formation of acid, there is a degree of defense against the acids in each mouth.[7] A large number of variables, many of which are present in most mouths, combine to render the acid harmless or to prevent its formation. The degree of protection in the population of so-called "civilized" countries is ordinarily not sufficient, so that most people suffer, to a greater or lesser degree, the ravages of dental caries. This is probably due to an increased rate of acid production in most cases, rather than to a decreased amount of protection. The reason is obvious in many instances, but there are still many factors that require further investigation.

On the basis of the above, whether or not all of the variables are thoroughly understood or known, there are several ways by which dental caries may be prevented. Many of these have been tried, either clinically or by means of laboratory experimentation, so is it now quite clear what must be done in order to prevent this important disease.[7] Since the acids are derived from fermentable sugar by enzymic action, it is obvious that by eliminating the sugars or by inactivating one or more of the enzymes, dental caries could be prevented. On the other hand, if the acids could be destroyed or rendered innocuous, either by neutralizing or otherwise removing them, or if the tooth could be rendered less soluble, caries could also be prevented. It has been shown beyond all reasonable doubt that the elimination of the substrate by dietary means is effective,[8, 9, 10] but only in cases where sugars are actually unavailable is this method generally successful. Numerous examples of enzyme inhibitors such as fluorides[11, 12, 13] Zephiran, [14] vitamin K,[15] ammonia[16] and urea,[17, 18] have been used experimentally with varying degrees of success. Rendering the tooth more resistant to acids (for instance by the use of fluorides,[11, 12, 13]) has also been successful. Thus it would seem that, from a practical and theoretical point of view, any method that performs any of the necessary functions of preventing the formation, or which rapidly neutralizes or destroys the acids, should prevent dental caries provided practical methods of application could be found.

One method of caries control that has been suggested frequently but has never adequately been tried experimentally[19] is that of simple oral hygiene procedures. If the maximum acid potential is reached about 20 minutes after the ingestion of sugars, a thorough cleansing of these substrates from the mouth, along with

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any acids formed within this interval of time, should prevent the initiation and progress of a carious lesion. There are several recognized methods by which this could be accomplished. A water or antiseptic rinse could be employed. This procedure probably would not remove much of the occluded debris or plaque material but, since the fermentable sugars are water soluble, it could conceivably dissolve and flush from the mouth much of the acids and fermentable sugars. There is little information available regarding the effectiveness of a rinse of the above type in removing sugars or acids from the mouth.

Another possible method — and one that is in general use for cleansing the mouth—is brushing the teeth. Although this procedure, with a suitable dentifrice, has long been advocated as a measure of general oral hygiene and has been practiced for generations, there are no reliable statistics regarding its effect on dental caries or its efficacy in cleansing the mouth. It is generally considered a good practice for reasons other than caries prevention. The usual routine has been to brush the teeth in the morning on arising and just before retiring. Theoretically, if the tooth-brushing procedure is to be effective in the control of dental caries, it must be performed immediately after each ingestion of sugar-containing foods. During the past few years this practice has been advocated intensely by dentists and research workers familiar with the carious process.[1, 20]

Although it is generally conceded that, if all sugars and acids were to be cleansed from the mouth before decalcification could occur, the incidence of caries would be reduced, there is little information concerning the efficiency of brushing in cleansing the teeth. A recent investigation[21] indicates that about 80 per cent of the debris can be removed by this process, but whether it can be removed before the acids can form and attack the enamel is problematical. For this reason, a comprehensive clinical experiment was started to determine the effect of proper brushing of teeth.

A great deal has been written on the proper type of dentifrice for the most efficient cleansing of the teeth. Some individuals feel that an antiseptic dentifrice should offer advantages over a non-antiseptic dentifrice, others that an antiseptic offers no advantage. Still others feel that a neutral or slightly acid dentifrice has superior cleansing effects to those of an alkaline dentifrice. Some argue in favor of a powder and some in favor of a paste. Others say that any dentifrice is simply a pleasant adjunct to an otherwise unpleasant task, and that a dentifrice serves no other purpose. The preponderance of evidence, however, indicates that an abrasive substance is necessary for proper cleansing. Because of financial limitations, it was impossible to test all types of dentifrices. Since tooth pastes are more widely used than powders, it was decided to use paste only. In this experiment an essentially neutral paste, an alkaline paste, and an antiseptic paste were investigated. The neutral paste consisted of dicalcium phosphate as the abrasive; glycerol; gums; flavor; a sulfated glyceride of coconut oil fatty acids as the detergent, and water. The antiseptic paste was identical with the neutral paste except that it had an efficient acridine derivative antiseptic present, and the alkaline paste was the usual precipitated chalk, soap type paste. This paper deals with the neutral paste only. The results of the other groups will not be available until a later date.

Experimental Procedure

A total of 946 individuals comprising 423 controls and 523 test subjects com-

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pleted the experiment. They comprised groups of liberal arts students from Drake University, Simpson College, and Emory University; the dental students of the University of Louisville, Emory University and Northwestern University, and the medical students of the University of Louisville. The groups were similar as far as possible in regard to oral conditions, age and sex. The average age of the test group was 22.7 and of the control group 23.5 years. Although there was a preponderance of males in both groups, the ratio of males to females was comparable.

All of those in the experimental group were instructed individually to brush their teeth thoroughly within 10 minutes after each ingestion of food or sweets, and when brushing was impossible to rinse the mouth thoroughly with water. They were instructed to brush their teeth with an accepted technic and to rinse the dentifrice from the mouth immediately after brushing. They were instructed to report the approximate number of times the brushing technic was omitted per day and, if they did not follow the technic after at least two meals per day continuously they were dropped from the experiment. Toothbrushes and dentifrice were supplied to all experimental subjects. Brushes were of a good quality and a standard pattern with twelve separated tufts of nylon bristle in two rows with the ends of the tufts cut wedge-shape.

The persons in the control groups were not supplied with dentifrices or brushes and were instructed to continue with their customary oral hygiene habits. The oral hygiene habits of all subjects except those in one group were determined and recorded. If the individuals brushed their teeth immediately after the ingestion of food, they were dropped from the experiment. In general, however, the oral hygiene habits of the control group were about the same as those of the test subjects previous to the experiment. Most of them ordinarily brushed their teeth only on arising and before retiring rather than after the ingestion of food. Only in exceptional cases were the teeth brushed only once per day or not at all. In general, the customary habit was to rinse the mouth free from dentifrice after brushing the teeth.

At the beginning of the experiment the teeth of each subject, in both experimental and control groups, were carefully examined by means of a mouth mirror, explorers, dental floss, and air syringe. Full mouth view and crown view roentgenograms were made for each experimental and control subject, with the exception of those from Simpson College and Drake University for whom crown view roentgenograms only were made. The roentgenograms were carefully examined by the original investigator with the aid of a magnifying glass and illuminator. After the original investigator had examined the roentgenogram and recorded his findings, the films were forwarded to a central office where another examination was made. Each roentgenogram was examined independently by two individuals, one of whom examined each of the roentgenograms of the entire test and control subjects. In cases where the two did not agree, the discrepancies were discussed with the two examiners and a conclusion reached. In case agreement was impossible, the area was omitted from the experiment. In the case of two groups, with the original investigator's consent, the discrepancies were judged by the second examiner and a third party.

At the end of one year and at the end of two years, the entire procedure was repeated. One control group, particularly the medical students, and a number of individuals in both groups, missed the examination at the end of the first year. Thus, for these exceptions, the caries experience for the two-year interval only is known. A number of individuals who started the experiment were dropped before the end of the first year. This was particularly true in the liberal arts schools where the students discontinued their

Table 1.—Comparison of test and control groups

	Control group		Test group		% Decrease test vs. controls
	Number of cases	Average number of new carious surfaces	Number of cases	Average number of new carious surfaces	
1st yr. clinical	306	2.21	526	0.82	63
1st yr. x-ray	308	0.87	528	0.32	63
2nd yr. clinical	146	1.11	422	0.82	26
2nd yr. x-ray	150	0.53	424	0.25	53
2 yrs. clinical	273	2.53	429	1.49	41
2 yrs. x-ray	271	1.34	429	0.53	60

education, but a few left the experiment because of a dislike of the procedure or because of noncooperation. The results were assembled in a central location and distributed to the various investigators before final statistics were compiled.

At the beginning of the experiment, and at six-month intervals, lactobacillus acidophilus counts were made according to the technic of Hadley.[22] This procedure was performed either at the institution concerned or, in the case of two groups, in the Iowa State Public Health Department. In one institution the acidophilus counts were discontinued after one year.

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Table 2.—Calculations for statistical tests of significance of differences between test and control groups

		Variance	Degrees of freedom	F	Probability of occurrence by chance alone
1st year clinical:	within groups	2.5797	830	144.95	less than .001
	among groups	373.9353	1		
1st year x-ray:	within groups	0.7757	834	76.77	less than .001
	among groups	59.5526	1		
2nd year clinical:	within groups	1.6441	566	5.537	between .01 and .05
	among groups	9.1026	1		
2nd year x-ray:	within groups	0.4710	572	17.70	less than .001
	among groups	8.3373	1		
2 years clinical:	within groups	3.7702	700	47.92	less than .001
	among groups	180.6643	1		
2 years x-ray:	within groups	1.3180	698	83.50	less than .001
	among groups	110.0564	1		

Table 3.—Calculations for statistical tests of significance of differences between test group and results of other studies

	Our test group			Other study	Average	t	Probability of occurrence by chance alone
	Number of cases	Average number of new carious surfaces	Estimated standard error of average				
1st year clinical	526	0.82	.05264	U.S.M.A.	2.2	−26.30	less than .001
				U.S.P.H.S.	1.5	−13.00	less than .001
				D & H	1.75	−17.75	less than .001
2nd year clinical	422	0.82	.12526	U.S.M.A.	2.2	−11.02	less than .001
				U.S.P.H.S.	1.5	− 5.43	less than .001
				D & H	1.75	− 7.43	less than .001
2 years clinical	429	1.49	.08235	U.S.M.A.	4.4	−35.29	less than .001
				U.S.P.H.S.	3.0	−18.29	less than .001
				D & H	3.5	−24.36	less than .001
1st year x-ray	528	0.32	.2830	Previous N.W.	1.2	−31.09	less than .001
2nd year x-ray	424	0.25	.02794	Previous N.W.	1.2	−33.92	less than .001
2 years x-ray	429	0.53	.04321	Previous N.W.	2.4	−43.29	less than .001

Results

The results were compiled on the basis of new carious surfaces that developed the first year, the second year and the sum of the two years. In all cases the results were compiled on the basis of (1) clinical examinations with the use of roentgenograms, and (2) roentgenographic evidence only. The latter is probably the only objective type of examination possible in this type of experiment. Although the DMF surfaces involved were recorded for the purpose of determining the similarity of the groups, they are not herein reported as this experiment is primarily concerned with the present caries activity rather than the total lesions present. The distribution of individuals according to the number of new carious surfaces in each experimental period was also recorded in the results. The results of the test group were then compared with those of the control group and with those of other similar groups studied previously. These results were then subjected to a statistical analysis.

At the end of the experiment, it was found that the individuals in the test group had a statistically significant lower incidence of dental caries than those in the control group. This was true whether the comparison was made on the basis of clinical or of roentgenographic evidence (Tables 1 and 2). When the results were compared with those of other investigators (Table 3, and Figs. 1 and 2) similar results were obtained, although in some cases a greater difference was observed. A further analysis concerning the distribution of the cavities (Table 4, Figs. 3, 4, 5, 6) indicates a general trend. Subjects with slight caries activity developed no cavities while the more caries active became less active.

The first year controls yielded results

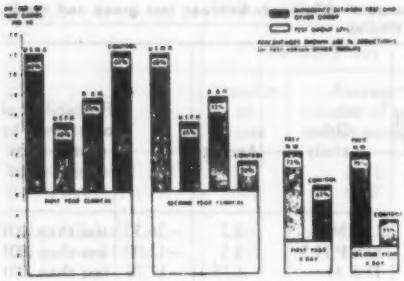

Fig. 1.—Comparison of average number of new carious surfaces developed per year, for test and control groups and other studies. First and second year results

identical with those found in students in the U. S. Coast Guard Academy[23] (2.2 new carious surfaces per year). This is slightly higher than the results of Hollander and Dunning, compiled from a study of 12,000 individuals in the Metropolitan New York area, wherein there was found an increment of 1.75 new carious surfaces per person in the similar age group. This was also higher than the U. S. Public Health Service statistics on similar age groups wherein there was found an increment of 1.5 cavities per year. The clinical results of the first-year group indicated an increase in carious surfaces of 0.8 cavities per person. This is a reduction of caries activity of 63 per cent when compared with the control group included in this experiment. The results are identical when compared with the individuals of the U. S. Military Academy. When the results are compared with the U. S. Public Health Service statistics[24] and those of individuals in the vicinity of New York City,[25] there is a reduction of 45 per cent and 53 per cent respectively.

Objective roentgenographic evidence on the first year study shows a 63 per cent reduction in caries activity compared with the controls. Unfortunately, there are few similar experiments recorded in the literature. The only other group with which to compare the roentgenographic evidence is that of previous students at Northwestern University.[15] Compared with this data, there is a reduction in caries activity of 73 per cent.

The results of the second year of the experiment show less reduction in caries activity than those of the first year. The average results of the test subjects are approximately the same in the first and second year of the experiment clinically and roentgenographically. The control subjects, however, showed less caries activity than they did the first year. Since

23. Arnold, F. A. Jr., Dean, H. T., and Singleton, D. E. Jr., Effect on Caries Incidence of a Single Topical Application of a Fluoride Solution to the Teeth of Young Adult Males of a Military Population. *J. D. Res.* 23:135 (June) 1944.

24. Private Communication.

25. Hollander, F., and Dunning, J. M., A Study by Age and Sex of the Incidence of Dental Caries in Over 12,000 Persons. *J. D. Res.* 18:43 (Feb.) 1939.

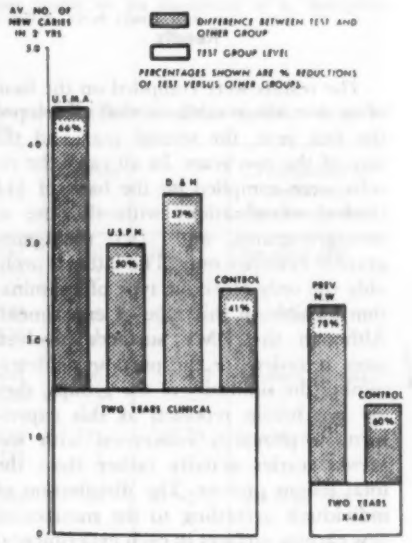

Fig. 2.—Comparison of average number of new carious surfaces in two years, for test and control groups and other studies

the control groups used no prophylactic measures, it is to be expected that the first and second years of the experiment should be fairly similar. The reason for this discrepancy is not clear, but two logical explanations could be offered. The error involved in the clinical examination may explain part of the differences. A breakdown of the data from the various schools indicates that the results may be partially explained on this basis, for the groups that changed examiners after the first examination are weighted quite heavily in this direction.

Another and more logical explanation is that news of the experiment was available to all who participated in it in four institutions, so that there may have been

Table 4.—Distribution of individuals according to number of new carious surfaces developed

Number of caries	Test group					
	1st year		2nd year		2 years	
	Clinical	X-ray	Clinical	X-ray	Clinical	X-ray
	(526 cases)	(528 cases)	(422 cases)	(424 cases)	(429 cases)	(429 cases)
0	55.70%	75.95%	57.58%	79.95%	35.20%	65.50%
1	21.86	17.99	19.43	16.04	25.64	22.61
2	13.50	4.54	12.09	3.30	17.72	7.46
3	5.90	1.14	7.11	.47	10.02	2.80
4	2.28	.38	2.84	—	6.29	1.16
5	—	—	.47	.24	2.10	.47
6	.19	—	.24	—	.93	—
7	—	—	—	—	.70	—
8	.38	—	.24	—	.70	—
9	.19	—	—	—	.47	—
10	—	—	—	—	.23	—
Total	100.00	100.00	100.00	100.00	100.00	100.00

	Control group					
	(306 cases)	(308 cases)	(146 cases)	(150 cases)	(273 cases)	(271 cases)
0	23.53%	53.25%	45.89%	68.67%	18.68%	38.74%
1	20.26	21.43	26.03	17.33	20.51	22.88
2	21.90	14.61	13.70	8.67	19.05	19.19
3	11.44	7.79	8.22	3.33	15.02	8.49
4	10.78	2.27	2.05	2.00	9.52	7.38
5	4.57	—	1.37	—	5.86	1.84
6	1.96	.33	2.05		3.30	1.48
7	2.61	.32			4.76	—
8	1.96		69		2.56	
9	.33					
10	.33					
11					.37	
12						
13	.33				.37	—
Total	100.00	100.00	100.00	100.00	100.00	100.00

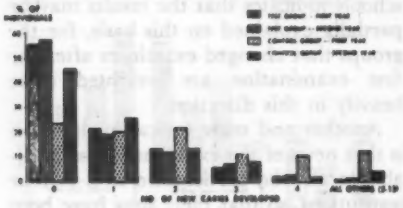

Fig. 3.—Clinical examinations for first and second years. Distribution of individuals according to number of new carious surfaces developed

a tendency for better hygiene practices in these control groups. In fact, in one institution a large percentage of the controls had to be dropped because they had changed their habits and were brushing their teeth immediately after the ingestion of sweets. Furthermore, during the time the experiment was under way, much publicity and interest on the part of the dental profession, as a result of the health education activities of the Council on Dental Health, encouraged people in general to use oral hygiene procedures immediately after eating. If this was the case, the reduction should be reflected in the roentgenographic study. The roentgenographic study does indicate a reduction in caries in the second year of examination. In any event, when the results of the test subjects are compared on a clinical basis with our own control groups and with the other available groups, it is found that there was a reduction in caries activity of 26 per cent. When compared with the statistics from the U. S. Military Academy, there is a 63 per cent reduction and when compared with the U. S. Public Health Service study and the one on individuals in the New York area, there are a 45 per cent and 53 per cent reduction respectively. The roentgenographic evidence indicates a reduction of 53 per cent when compared to our own controls and a reduction of 65 per cent when compared with the previous students of Northwestern University.

Unfortunately, since there has been no similar two years' study on the incidence of dental caries, it is impossible to compare the data of the two years' study with other groups without projecting the data of the previous one-year studies to two years. According to the data obtained by Hollander and Dunning on 12,000 individuals in the vicinity of New York City, the annual increase in carious surfaces does not change appreciably between the ages of 17 and 34. These investigators found that the annual increment of new carious surfaces was 1.75. If this data is correct, then the subjects from the U. S. Military Academy would develop 4.4 cavities, and those studied by the U. S. Public Health Service 3.0 cavities, in the two-year period, whereas those in the vicinity of New York City would develop 3.5 new carious surfaces in two years. On this basis, a comparison with the two years' study would indicate a reduction of 63 per cent, 45 and 53 per cent for the U. S. Military Academy, the U. S. Public Health Service, and the New York group statistics respectively. On the basis of the above work, it is plain that the reduction in carious

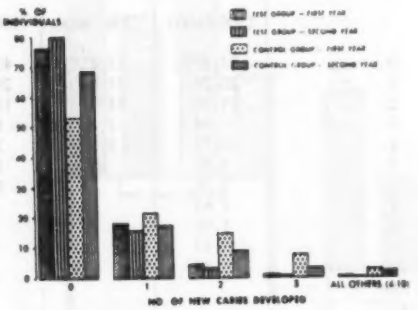

Fig. 4.—Roentgenographic examination for first and second years. Distribution of individuals according to number of new carious surfaces

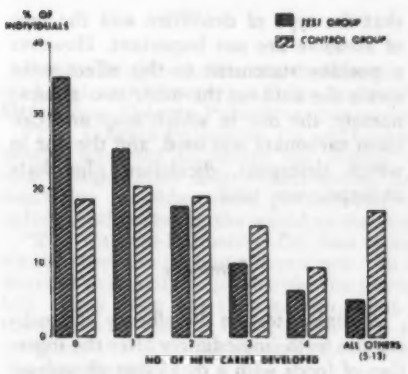

Fig. 5.—Clinical examination for total two years. Distribution of individuals according to the number of new carious surfaces developed

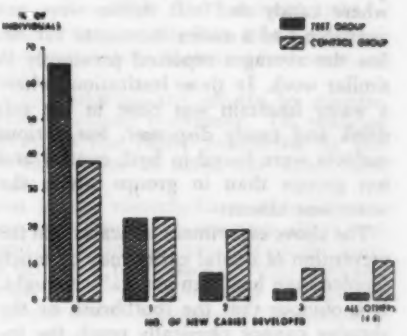

Fig. 6.—Roentgenographic examinations for total two years. Distribution of individuals according to numbers of new carious surfaces

activity by purely oral hygiene procedures is real and that the actual reduction is probably in the neighborhood of between 50 and 60 per cent.

Discussion

In any experiment of this type there are many factors that may alter results. Every effort was made to minimize these factors and at completion the data was subjected to rigorous statistical analysis. The evidence indicates that the values are significant with the possible exception of the second year clinical data. Here the probability of the differences due to chance is between one and five in one hundred, whereas in all other comparison the probability of chance occurrence is less than one in one thousand. Analysis reveals that the controls in the second year clinical study show a low incidence of caries rather than the test group showing a high incidence. A large number of individuals in these control groups were in schools where there were also individuals in a test group, and a number were dental students. Although it is definitely known that these control individuals did not use the after-meals brushing technics, it is felt by the primary investigators observing them that, during the second year, they unconsciously used better hygiene technics and rinsed the mouth after eating. When the results of the test groups are compared with the data from other sources, the degree of caries reduction remains high and is statistically significant.

One striking result of the brushing technic is the large numbers of individuals that developed only a few cavities during the one and two-year periods. Thus it seems that brushing the teeth immediately after eating will materially reduce the numbers of cavities, not in just the least susceptible, but also in those cases where a multitude of cavities would otherwise develop. Those individuals who are only mildly caries-active develop no caries and the very active ones develop only a few lesions.

It should be recorded that in general all of the individuals in both the test and control groups had soft drinks and candy readily available during the day with the exception of one control group. This factor was reflected in the variations from

group to group. The control in the school where candy and soft drinks were not available had a caries increment far below the averages reported previously in similar work. In those institutions where a water fountain was close to the soft drink and candy dispenser, less carious surfaces were found in both control and test groups than in groups where the water was absent.

The above experiment indicates that the prevention of dental caries may be much simpler than has been generally thought. It is obvious that the toothbrush or the abrasive cannot physically reach the inner portions of the proximal areas. Hence it is to be expected that the forcible dilution of the material in these areas might account for the results. There is considerable evidence to substantiate this possibility.

In view of the favorable results reported above with the unmedicated dicalcium phosphate dentifrice, it is possible that the type of dentifrice and the type of abrasive are not important. However a positive statement to this effect must await the data on the other two groups; namely, the one in which soap and calcium carbonate was used, and the one in which detergent, dicalcium phosphate antiseptic was used.

Summary

A clinical test on the efficacy of brushing the teeth immediately after the ingestion of foods with a dicalcium phosphate detergent dentifrice, indicates that dental caries can be materially reduced by this method. The results indicate that by means of simple oral hygiene procedures dental caries activity can be reduced. The results are in accord with the generally accepted theory of the carious process and materially strengthen this theory.—*311 East Chicago Avenue.*

Triple the Ante.—J. O. Mercer, chairman of Council, British Medical Association in New Zealand, recently told the Canadian Medical Association that with only 1,800 doctors under the government health insurance plan, the annual cost of drugs alone has risen from £500,000 ($2,000,000) to £1,500,000 ($6,000,000). The government will not release any figures on the cost of the system but it is known that it has far exceeded the original estimate, and is increasing yearly. The fee-for-service plan is used and about 5 per cent of the doctors are profiteering on it. One doctor took £50,000 ($200,000) out of the fund in one year.—*From an editorial in Vol. 10, No. 7, July 1949, North Carolina Medical Journal, p. 381.*

COLGATE-PALMOLIVE CO.,
New York, N. Y., July 18, 1958.

Commenting on testimony before the House of Representatives Subcommittee on Legal and Monetary Affairs headed by Representative Blatnik (Democrat, of Minnesota) Colgate-Palmolive spokesman said:

"The Colgate-Palmolive Co. enthusiastically endorses any efforts by governmental agencies to insure the safety of the American consumer. Of possible equal importance and effectiveness, however, is the effort conducted by the dentifrice manufacturers themselves, over the years, to bring the finest and safest toothpastes in the world to the consumer.

"The Colgate-Palmolive Co. has pioneered in the manufacture of toothpaste since before the turn of the century. In those early years, the research effort was devoted primarily to producing the purest and most pleasant product on the market. Very little was then known about the causes of tooth decay. The accepted thought was that 'a clean tooth is a healthy tooth' and Colgate's toothpastes certainly provided the necessary cleansing properties to supplement the action of the toothbrush.

"In the 1930's, however, new concepts on the causes of caries (tooth decay) came into being. The action of the carbohydrates to produce decay-causing acids that attack the teeth created new research efforts on the part of Colgate scientists.

"Since that time, Colgate-Palmolive has conducted many large-scale research projects in an effort to develop the chemical additives best suited to combat the enzyme action on carbohydrates. These studies have been conducted not only in Colgate's own research laboratories, but also by leading dental research authorities in university laboratories.

"It was these Colgate studies which led to the discovery of Gardol (the company's trade name for sodium-N-lauroyl sarcosinate). The effectiveness of Gardol was substantiated by large-scale clinical tests in several geographical locations throughout the country.

"Advertising has played a major role in building America's economy. Colgate-Palmolive Co.'s advertising—while functioning in an area of competition in keeping with the traditional American concept which has produced the highest standard of living in the world—is consistent with the goals and objectives of professional societies and governmental agencies. Its advertising claims are supported by its research.

"As the world's leading producer of toothpaste, Colgate-Palmolive Co. has over the past 10 years also assumed the leadership in dental research by supporting and conducting extensive research projects in the field of oral hygiene.

"While many of these, of course, have contributed to substantiating its advertising claims or in improving its products, many others have made valuable contributions in other research areas. The establishment of the company's division of dental medicine on the campus of Rutgers University is an excellent example. Here, Colgate scientists work on pure basic research of value to the health of the American people.

"An example noted recently in the public press, was the discovery of a new method for the detection of cancer, developed by Dr. J. Migliarese of Colgate-Palmolive Co. research staff, and turned over by the company to the National Institutes of Health for further study and development.

"Better dental health is as much an objective of the Colgate-Palmolive Co. as it is of the dental profession and the regulatory governmental agencies. All three have contributed to the betterment of dental health and the Colgate-Palmolive Co. is happy to continue to function in a responsible and constructive manner, as it has in the past under the free-enterprise system to help make certain that the dental health of the American public will continue to improve in the same rapid pace as in the recent past years."

EXHIBIT 7

Amounts spent for oral hygiene products

Product	1956	1955	1954
Dentifrices	$155,340,000	$152,950,000	$147,860,000
Chlorophyll toothpastes	10,760,000	14,690,000	23,170,000
Other toothpastes	136,550,000	129,790,000	115,280,000
Toothpowders	7,840,000	8,280,000	9,200,000
Liquid dentifrices	190,000	190,000	210,000
Denture products	15,680,000	14,250,000	12,750,000
False-teeth adhesives	9,090,000	8,250,000	7,400,000
False-teeth cleansers	6,590,000	6,000,000	5,350,000
Other oral hygiene products	94,470,000	86,860,000	82,630,000
Toothbrushes	53,040,000	50,440,000	47,860,000
Dental floss	2,110,000	1,930,000	1,770,000
Mouthwashes and gargles	39,320,000	34,490,000	33,000,000
Total for oral hygiene products	265,490,000	254,060,000	243,240,000

NOTE.—Amounts given are estimates of civilian spending in all types of stores.

Source: Drug Topics, Aug. 5, 1957.

Drug Trade News, July 28, 1958, on page 22 lists the following new information on expenditures for dentifrices during 1957:

Dentifrices (total)	**$210,280,000**
Toothpaste	**202,340,000**
Chlorophyll	**3,700,000**
Other	**198,640,000**
Toothpowders	**7,760,000**
Liquid dentifrices	**180,000**

Brand-by-brand listing of 1957 ad expenditures for drug-trade products

Product	Total	General magazines	Farm magazines	Newspaper sections	Network TV	Newspapers	Spot TV
Amident	$66,770					$28,950	$37,820
Brisk toothpaste	355,410				$355,410		
Colgate dental cream	5,892,314	$1,084,632	$60,100	$20,145	2,925,610	1,801,827	
Crest	2,668,765	1,008,675		35,200	1,457,810	26,000	141,080
Dr. Lyon's dentifrices	307,330						307,330
Gleem toothpaste	8,980,224	1,292,082			6,188,530	98,962	1,400,650
Iodent toothpaste/powder	25,986	25,986					
Ipana	4,343,993	921,527			2,968,196		454,270
Listerine toothpaste	108,850				[1]		108,850
Pepsodent	1,248,620					950,960	297,660
Phillips toothpaste	279,356				279,376		
Stripe toothpaste	259,747					259,747	
Total	24,537,365						

[1] No actual data available.

Source: Drug Trade News, June 16, 1958.

EXHIBIT 8

DISCUSSION OF "BAD BREATH" CLAIMS

By Donald A. Wallace, professor of applied materia medica and therapeutics, University of Illinois College of Dentistry

DEFINITION OF TERMS

In advertising for certain dentifrices, references to "breath odor" (BO) and "mouth odor" (MO) appear. "Breath odor" is a comprehensive term. It covers all the smells emanating from the linings of the mouth and the entire respiratory tract. "Mouth odor" includes only those odors arising from the oral surfaces. Needless to say, not all mouth odor or breath odor is objectionable.

It is necessary to distinguish carefully between breath odor and mouth odor. Conditions in the mouth account for only a fraction, perhaps 50 percent, of the cases of malodorous breath. Less than this, perhaps 35 percent of all the cases of malodorous breath can possibly be mitigated by the proper use of a dentifrice and toothbrush. This is because the sources of the breath odor lie in the respiratory tract in about half the instances, and, of the half that are in the mouth, about 30 percent or so are caused by inaccessible filth or by diseases which cannot be controlled by oral hygiene.

Some cases of malodorous breath are attributable entirely to oral filth or to food debris. Since use of the brush, with or without a dentifrice, can help to clean oral surfaces, it is reasonable to suppose that oral hygiene would lower the intensity of mouth odor in some mouths. Unfortunately, many of us do not know when our breath is offensive. In many instances, even after we know we are offending, we cannot unearth the cause or get it remedied without professional help. It is not likely that any biologically sound method would deodorize the mouth completely.

MEASUREMENT OF ODOR

Odor is usually associated with animal or vegetable matter. It has two aspects which can be observed and recorded. It has quality; for example, onionlike, sweetish, rancid, yeasty, putrid, aromatic or fresh. It can also be described as pleasant or unpleasant. Regardless of its quality, odor can vary in intensity. This is a quantitative aspect and can be measured. Adults have customarily been used as test subjects for such measurements. When odors which originate in adult mouths are strong, they are objectionable to most people. It is therefore defensible to select a certain level of adult mouth odor intensity as offensive. Such a policy narrows the applicability of the findings to adults, of course.

Odor intensity can be measured by sniffing or by forcefully introducing vapors from odoriferous material into the nose. It can also be estimated chemically, but chemical means are applicable only when the odoriferous substance can be isolated and is uniform in chemical nature. Mouth odor is caused by a variable mixture of substances, and it is therefore not susceptible to chemical measurement. The methods which have been generally adopted for measurement of mouth odor and breath odor depend upon sniffing.

Sniffing tests fall in two categories. In one kind, a measured volume of the vapor from the mouth is diluted with graded volumes of pure air until the technician who is sniffing can no longer detect any odor. The larger the volume of diluting air required, the higher the value assigned to the mouth odor. Depending upon the investigator and the instrument he uses for diluting the odorous vapors, the odor intensity numbers are designated as pO values, odor threshold numbers (OTN), and otherwise.

In the second type of sniffing test, a panel of trained technicians is offered samples of odorous mouth vapor to smell. These technicians assign a number to each sample, based upon its odor intensity.

All sniffing tests are subjective. All select some level of odor more or less arbitrarily as being objectionable and all produce results which have some significance. Our concern need not be with the somewhat unsatisfactory methods for measuring mouth odor, or with human error in carrying out the technical procedures, but with the interpetation of the values obtained.

Incidentally, devices used to dilute odorous vapors quantitatively are called osmoscopes or osmographs. There are several different varieties, not all of which are adequately described in the literature. Their relative merits are controversial, but it is not necessary to understand the details of their design or operation in order to evaluate odor claims made for dentifrices.

In support of its claims for Gleem toothpaste, Procter & Gamble submitted exhibits with a letter to the subcommittee dated March 25, 1958. I would like to comment on the content of exhibit 2.

The first paragraph of this exhibit will be passed over, because it does not deal with mouth odor.

Claims in controversy are stated in the exhibit as:

Claim 2: "To get . . . protection against mouth odor all day—always start the day with Gleem.

"Mouth odor stopped all day with *one* Gleem brushing. Scientific odor-measuring tests prove brushing with Gleem before breakfast gives most people *all-day* protection against mouth odor . . ."

The exhibit continues:

"Clinical experience reported in the literature (Collective Review-FETOR EX ORE, M. Massler, D. D. S., M. S.; R. D. Emslie, B. D. S., M. S.; T. E. Bolden, A. B., D. D. S.; Oral Surgery, Oral Medicine and Oral Pathology, January 1951) points out that odors originating in the mouth are probably caused by the bacterial putrefaction of food debris and saliva."

The article cited above is a competently written review of the literature on breath and mouth odor supplemented by observations made by the authors, who are dentists. It deals with the historical aspects, measurements of mouth and lung odors, the odor of normal breath at various ages and in various species of animals, and the origin of breath odors. Treatment is also discussed.

Under Origin of Local Fetor ex Ore, retention of food around the teeth, putrefaction of saliva, and the presence of oral disease were given about equal emphasis. In its statement, quoted above, the firm overlooks the stress which the article places on factors which its dentifrice could not be expected to control, such as oral disease.

The exhibit continues:

"Gleem's mouth odor claims are based on tests carried out by Procter & Gamble and by Evans Research & Development Corp., 250 East 43d Street, New York, N. Y. Our own work on mouth odor had shown that brushing with Gleem had an effect much greater than could be accounted for by any short-lived masking effect of the flavor ingredients. As a result, we asked Evans, an independent research laboratory with considerable experience in odor evaluation, to do further work. A trained sensory panel in the Evans organization made 2,425 observations of mouth odor levels. The study was done in three series of evaluations as follows:

1. *Pilot study to test procedure.*—This study was run for 5 consecutive days during which period the subjects had breakfast as usual but did not brush their teeth with Gleem until after the first, or control, observation for mouth odor was made at 9:30 each morning. As indicated on the graph attached to the exhibit, mouth odor level showed a 2-point drop after brushing with Gleem and remained at a significantly lower level through the day. Thus, mouth odor level went down and stayed down.

2. *Study to measure the effect of no brushing on mouth odor level.*—The second series of evaluations were conducted for 4 consecutive days during which period the subjects did not brush their teeth at all. Observations were made throughout the day to check the level of mouth odor. As indicated on the attached graph, mouth odor level remained high and never went down to the lower level achieved by those subjects who did brush their teeth.

3. *Same study as pilot study, expanded to confirm results.*—The final evaluation with a larger group of subjects ran for 2 consecutive days. The subjects had breakfast at home but did not brush their teeth with Gleem until after the first, or control, observation for mouth odor was made at 9:30 each morning. Additional checks were made throughout the day. As indicated on the attached graph, the mouth odor level showed a drop of almost 3 points after

brushing with Gleem and remained at a significantly lower level throughout the day. As in the pilot study, mouth odor level went down and stayed down."

Only averages are given on the graph referred to above. The average mouth odor level in the absence of brushing (item 2) was 6 units at 9:30 and averaged about 5.5 for the period to 4 o'clock. The group reported under item 1 averaged about 4.4 before brushing, dropped to about 2.3 after brushing, and rose to about 3.3 during the rest of the test period. The group referred to in item 3 averaged 6.2 before brushing, 3.4 immediately after brushing, and 4.3 during the rest of the test period.

While it is stated that 2,425 "observations" were made, it is not possible to tell how many subjects (individuals who were subjected to test) were used. The exhibit does not say that the mouth odor of any of the subjects was objectionable at any time. In fact, the population tested is not described. The baseline measurement of odor intensity was made at 9:30 in the morning, after breakfast. It is generally known that mouth odor usually falls and levels off shortly after breakfast. It is not surprising, therefore, that brushing with Gleem made little difference in mouth odor intensity under the stated conditions. Observations were taken until 4 p. m., only 6½ hours after brushing. This can hardly be considered "all day" or "through the day."

All the data in this section of the exhibit were obtained by a panel method. The meaning of the values and the details of the observations are not given. It is therefore not possible to evaluate many aspects of the tests.

In the remainder of the exhibit, an experiment conducted by employees of the firm is described. Six women and ten men gave samples of "mouth odor" as soon as possible after arising and without having eaten, smoked, brushed their teeth, or taken water. Teeth were brushed immediately thereafter with Gleem, the subjects ate breakfast, and gave another set of mouth odor samples. Additional odor samples were collected just before lunch, immediately after lunch, and about 3 hours after lunch.

The exhibit concludes:

"Of the 16 people on the panel, only 5 provided any samples having a score of 8 (offensive) or more at any time on the same day after having brushed their teeth once (before breakfast) with Gleem. In this study, then, there were 11 out of 16 (7 out of 10) people who, after brushing before breakfast with Gleem, did not have an offensive mouth odor during the day."

The numerical values given in the above paragraph were obtained by a different method than those reported by the Evans panel, and the Evans numbers presumably cannot be compared directly with them.

The nature of the population is defined very sketchily, only the number of each sex and the fact that they were adults being mentioned. It is not stated whether the odors from the mouths of the 16 subjects were offensive at the beginning of the test.

A basic weakness in the test is the fact that breakfast and brushing took place between the collection of the first and second samples. Thus it was impossible to tell which factor, breakfast or brushing, influenced the odor intensity values obtained after brushing.

One might infer from the information in the exhibit that brushing and breakfast took place between 8 and 9 o'clock in the morning and that the after-brushing values were obtained over a period of about 6 or 7 hours. It is obvious that 30 percent of the 16 subjects exhibited offensive breath, by the firm's criteria, by 4 o'clock or so.

Moreover, in none of the studies was a control test made in which the subjects used only a toothbrush, without Gleem toothpaste. The mechanical removal of residues by the brush itself may be expected to give improved odor ratings. The essentiality of Gleem in producing the results observed after brushing was not tested at all.

In summary, the exhibit does not justify the claims "protection against mouth odor all day * * *" and "Mouth odor stopped all day with one Gleem brushing." There is nothing in it to suggests that mouth odors were "stopped" in any of the subjects for any period of time.

In connection with the bad breath prevention claims for Ipana toothpaste, the Bristol-Myers Co. submitted a report by its consultant, Dr. Louis C. Barail, dated April 5, 1957. The following are pertinent excerpts:

"The purpose of this study was to establish the efficiency of Ipana toothpaste in removing mouth odors of local origin after various periods of time.

"SELECTION OF SUBJECTS

"Fifty subjects of both sexes participated in this investigation. Twenty-six males and twenty-four females were selected from a greater number of individuals in order to meet the following requirements:

"1. The original odor threshold numbers (OTN's) of the mouth odor before brushing the teeth should be above 8.6, therefore above average.

"2. The odor should be due to local causes only.

"In order that the odor to be measured could not be attributed to any extraneous causes, the 50 subjects were instructed not to eat spicy foods or condiments during the day preceding the tests. They were not allowed to brush their teeth before the first OTN determination.

"BRUSHING AND RINSING PROCEDURE

Each subject was given a Tek medium toothbrush and a tube of Ipana. Approximately 1 gram of dentifrice was evenly applied on each brush. He then brushed his teeth in his usual manner for 45 seconds, rinsed his mouth three times with approximately 1½ ounces of water each time, and rinsed his toothbrush in running water. He brushed his teeth again for 30 seconds, rinsed his mouth thrice as before, and was dismissed until the next OTN determination. Brushing and rinsing were timed by means of a stop watch."

Odor threshold numbers (OTN values) were determined before brushing and 4 and 9 hours after brushing. Odor was detected in 28 of the 4-hour samples and in 37 of the 9-hour samples. All OTN's were below 8.6 (the value chosen as objectionable) at 4 hours. After 9 hours, all OTN values were lower than the original ones, but 7 were 8.6 or above.

The following important information is not given in the report:

1. Ages of test subjects.
2. Conditions under which "original" OTN's were measured.
3. Time of day brushing was done.
4. OTN values obtained over a similar period without brushing the teeth.

The data cover a period of only 9 hours. They indicate that approximately 14 percent of the subjects developed objectionable mouth odors between 4 and 9 hours after thorough brushing with Ipana. It is not possible to tell from this report how many would have developed objectionable mouth odors if they had not brushed with Ipana.

The data certainly do not justify claims such as "Not a whisper of bad breath" and "* * * prevents bad breath." Note that the firm says "breath" and not "mouth odor." The claims would be misleading even if they were limited to mouth odor, since people often cannot tell where odors originate. Use of the term "bad breath" is more misleading.

NOT A
WHISPER OF
BAD BREATH
WITH NEW IPANA
...its distinct taste tells you so
• New Ipana® Tooth Paste with germ-killing WD-9 prevents bad breath. Use it regularly. Ipana's distinct taste and refreshing after-taste tell you it cleans your entire mouth.
• Ipana with WD-9 actually has twice the decay-germ killing power of any other leading tooth paste. So it can help your children fight tooth decay effectively, too.
ipana
TOOTH PASTE

EXHIBIT 9

THE TOBACCO INSTITUTE, INC.,
Washington, D. C., August 7, 1958.

HON. JOHN A. BLATNIK,
Chairman, Subcommittee on Legal and Monetary Affairs, Committee on Government Operations, House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is to place, through your indulgence, in your committee's record of the hearings on false and misleading advertising of dentifrices, in which questions on the health aspects of tobacco use were introduced, the following evidence of the scientific unsoundness of implications by testimony that the so-called tars from cigarette smoke are involved in specific health problems.

Proposals made before your committee regarding cigarettes are based on assumptions that do not find substantial backing in scientific evidence.

In this connection I quote from a statement of mine issued to the press on July 29:

"* * * During Congressman Blatnik's hearings on the cigarette question last summer, testimony was presented by such scientists as:

"Dr. Ian Macdonald, clinical professor of surgery, University of Southern California School of Medicine, Los Angeles, Calif., who said:

" 'The total evidence here reviewed fails to establish any sound basis on which a causative influence may be assigned to cigarette smoking in the production of cancer of the lung.'

"Dr. R. H. Rigdon, professor of pathology, University of Texas Medical Branch, Galveston, Tex., who testified:

" 'It is my opinion that the data on which the relation of cigarette smoking to lung cancer is based are not sufficient to justify the conclusions which have been drawn by certain statisticians.'

"Dr. Harry S. N. Greene, chairman, department of pathology, Yale University School of Medicine, New Haven, Conn., who told the committee:

" 'The methods used in statistical inquiry raise doubts that the results convey a suggestion of causal relationship between smoking and lung cancer. The direct experimental approach also has not succeeded in supplying evidence of such a relationship.' "

This statement is consistent with an objection recorded with the Reader's Digest recently concerning that magazine's articles on cigarettes making misleading representations to the effect that specific health gains would result by reduction of solids and nicotine in cigarette smoke. This letter is as follows:

JUNE 23, 1958.

Mr. DEWITT WALLACE,
The Reader's Digest,
Pleasantville, N. Y.

DEAR MR. WALLACE: The title of the article "The Cigarette Industry Changes Its Mind" in the July 1958 Reader's Digest is not in accord with fact. The implications of this piece are most unfair to the tobacco industry and misleading to the general public.

Readers should know that this article is another in your magazine's series of anticigarette attacks that date back about 20 years. This latest piece is based on opinions about smoking that are biased and selected.

The cigarette industry has not changed its mind. Our position was and is based on the fact that scientific evidence does not support the theory that there is anything in cigarette smoke known to cause human lung cancer.

There has been much intensive research on this subject in the past 5 years, including that supported by several segments of the tobacco industry, the Tobacco Industry Research Committee. To my knowledge, none of this work has resulted in identifying any substance in condensed tobacco smoke (which you refer to as tars) that is known to be cancer-causing to man or to be present in sufficient quantity to be cancer-causing to laboratory animals.

As far as the article's discussion of filter cigarettes is concerned, the production and marketing of filter cigarettes are matters of individual company competitive business. Anyone familiar with the tobacco industry knows that tobacco manufacturers constantly compete with each other to make products to please their customers. That is the reason there are cigarettes with different lengths, shapes, flavors, mouthpieces, tobacco blends, containers, filters, and even colors.

The Tobacco Institute believes that the health of the people is more important than dividends for any industry. We are equally convinced that the American people believe in fair play for an industry that historically began and grew with the life of our country, all the while providing work for and contributing to the contentment of millions.

It is right that the truth should be told about tobacco or anything else, but complete truth is never told on one side of a coin. The other side, in this case, is that many scientific experts believe there is no legitimate proof that cigarette smoke causes human cancer. This side you have failed to tell.

Sincerely yours,

JAMES P. RICHARDS.

The recognition of lack of evidence to support the theory of a substance or substances in tobacco that is a specific cancer danger is given in a July 7, 1958, statement from the United States Public Health Service which contained this assertion:

"The factors in heavy and prolonged cigarette smoking which may cause lung cancer have not been demonstrated by clinical or laboratory research."

Of particular and direct relevance, however, is a section of a report just published by the British Empire Cancer Campaign. The section which follows comes from Prof. R. D. Passey of the Chester Beatty Research Institute:

"The experiments described in the annual report for 1956, in which tar from English and American cigarettes has been applied to the skin of the same strain of white Swiss mice in use in Wynder's experiments are complete.

"In contrast with the original experiments in which English tar only was applied to 5 well-known strains of laboratory mice and in which no malignant tumors were induced, in this case 2 epitheliomata and 3 papillomata were obtained from English tar and 3 epitheliomata, 1 subcutaneous sarcoma, and 6 papillomata from American tar.

"It is difficult, however, to know how to interpret these results in that the mice (which were obtained from the same American source as those in use in Wynder's experiments) in this laboratory suffered from frequent extensive spontaneous ulcerations. In view of Deelman's original experiments, in which he showed that the application of coal tar to an area of skin previously injured (in his experiments by simple incision) gave rise to tumors in the area of injury, it is doubtful if this particular strain of mice, with its liability to spontaneous skin ulceration, is a suitable one for such tests.

"There is no evidence that this condition resulted from the tar applications, because the ulcerations appeared frequently in the acetone controls, and indeed in controls entirely untreated. In this strain, leukemia is frequent and pulmonary adenomata occurred in nearly every animal over a year old.

"On account of these pathological conditions, these experiments with this strain of mice cannot be interpreted satisfactorily. However, the experiments suggest that the tars from American and English cigarettes, when produced under the same conditions, are of similar activity, but are considerably less carcinogenic than Wynder's tar. Taken in conjunction with the earlier experiments and those reported in these annual reports from other laboratories in Great Britain, it is clear that the carcinogenic action of cigarette tar on the skin of mice is a weak one * * *"

Your committee has previously heard expert testimony that mouse-skin painting results cannot be interpreted as applying to man.

Perhaps of more direct concern are inhalation experiments with animals using cigarette smoke.

Professor Passey, who was just quoted above, also reported this:

"The continuation of the exposure of rats to the smoke of 25 cigarettes a day has not resulted in any malignant tumor.

"On the other hand in the control animals a spontaneous lung cancer has occurred at the age of 565 days. Moreover in old stock breeding rat 596 days old, another spontaneous lung cancer has been found. In each case the tumor was associated with bronchiectasis and might easily have been overlooked.

"This observation disposes of the suggestion that rats are unsuitable animals for such experiments on the grounds that they are not naturally subject to lung cancer."

In addition, there have recently been at least four other public reports of scientific experiments that fail to substantiate the theory that inhalation of tobacco smoke is cancer-inducing to lungs, even of experiment animals. These are:

1. Dr. Cecile Leuchtenberger of the Institute of Pathology at Western Reserve University reported in July to the International Cancer Congress in London that "in none of the mice which had been exposed to smoke of up to 1,500 cigarettes over a period of nearly 2 years has an invasive carcinoma been found."

2. Prof. P. R. Peacock, of Glasgow, also reported to the congress in London that "fowls, pigeons, hamsters, desert rats, wistar rats, and rabbits have been trained to receive directly into their buccal cavity cigarette smoke from a manually operated apparatus * * * No primary bronchogenic tumors have been observed in any species."

3. Drs. Condict Moore and A. James Miller, of the School of Medicine of the University of Louisville, Kentucky, reported in the May 1958 issue of the AMA Archives of Surgery that no cancers were produced in hamsters following a variety of applications of whole "tar" from cigarette smoke over many months.

4. Drs. Giuseppe Della Porta, Leonard Kolb, and Philippe Shubik, of the Chicago (Ill.) Medical School, reported in Cancer Research for June 1958 that administration of tobacco "tar" by tube directly into the tracheobronchial trees of hamsters over long periods of time produced no cancers.

The significance of such lack of substantiating evidence was thoughtfully summed up in an editorial in the Springfield, Ohio, Sun of June 25, 1958:

"A PROPHET IN THE SMOKE

"For about 5 years now the American Cancer Society has been at the forefront of the anticigarette chorus, howling away mightily. All that time cigarette manufacture has been growing steadily—from 369 billion units a year to 410 billion, and an estimated 425 billion for 1958.

"One can appreciate therefore, a certain sense of frustration in the Cancer Society. It isn't altogether a matter of a prophet's being without honor in his own country; it's also a matter of prophecies being sharply disputed by other prophets, equally respectable. The statistical relationship between lung cancer and cigarette smoking is provocative, but it is a statistical relationship only and there are many statisticians as well as medical authorities who question the deduction of a pathological relationship therefrom. The Cancer Society's own researchers and pathologists seem as far today as ever from establishing even experimental proof that cigarettes cause cancer.

"That may explain the more than slight trace of asperity that creeps into the public utterances of some Cancer Society spokesmen. The other day, for instance, the society's Dallas outpost was listening to a talk by a Dr. Robert J. Samp, of the cancer research staff at the University of Wisconsin Center. As the speaker addressed his audience he became more and more peeved at the clouds of tobacco smoke drifting up from the auditorium. Finally, unable (like Jeremiah) to contain himself, he burst out:

" 'Nothing makes me angrier than to watch a person take a puff, and smile and say, "Well, if I'm gonna go, it's a wonderful way to go." He will go all right, and there's an excellent possibility the way will not be wonderful.'

"If an annoyed prophet, Dr. Samp was at least too much the scientist to make his prophecy any more explicit. As it stands none can disagree, for we all have to 'go' sooner or later and 'the way' is not usually 'wonderful' no matter what ailment carries us off. But we were reminded once again of the strong Puritan influence in so much of the anticigarette preachments. Dr. Samp, for example, leaves himself wide open to the suspicion that what he resented as much as anything was the spectacle of so many of his listeners enjoying themselves with the weed he pronounces to be noxious.

"Who can blame him? Prophets are human, too, but this incident in its turn reminded us of the stand taken by 17th century Puritans against the cruel sport of bear beating. The Puritans opposed it (they opposed evrything, of course, but notably this) not because it caused distress to animals but because it gave pleasure to human beings.

"It would be nice to think that Dr. Samp, relenting of his severity, has gone back to his laboratory to devise some means of eliminating the carcinogenic (cancer-making) ingredient in tobacco. But that could hardly be, for nobody has as yet conclusively demonstrated the existence of such an ingredient in tobacco. As that old English recipe for rabbit pie has it: 'First, catch a rabbit.' "

These citations are submitted because it is hoped that they will be taken into serious consideration in your further deliberations on this subject in the future.

Very sincerely yours,

JAMES P. RICHARDS.